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USE OF CLINICAL SIMULATION IN DEVELOPMENT OF CLINICAL INFORMATION SYSTEMS

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PREFACE

This thesis is submitted to obtain the PhD degree at the department of Planning and Development at Aalborg University. The work described in the thesis was carried out between October 2011 and October 2014.

Having worked in health informatics for more than ten years, I have experienced the gap between clinical information systems and the work practice they are intended to support. My background of 20 years of nursing and further education as B.Sc. Computer Science and M.Sc. in Health Informatics has helped me to gain insight into both fields. Many attempts have been and still are made to involve users, extend the dialog and improve understanding between developers and users, but user involvement and dialog may be conducted in various ways with very different outcomes.

In 2007 I managed the establishment of the IT Experimentarium (ITX) in the Capital Region of Denmark. Since then I have managed clinical simulation in the region. Performing clinical simulation has given us an opportunity to focus on both clinical context and users and, through simulation, clinical scenarios may come alive without causing any harm. Simulation gives the users a voice and improves communication between developers, end-users, and the IT-department. Furthermore, replicating specific scenarios gives us an opportunity to form a mutual understanding as it creates common ground for dialog and discussion.

Three years of research have not only enhanced my knowledge of clinical simulation and the potential uses of simulations, but also broadened my understanding of science, methodology and socio-technology and enlarged my network of fellow health "informaticians". My view of user involvement, system development, and use of clinical simulation is far from what it was three years ago.

It has been a long journey but I have enjoyed every minute.

Sanne Jensen
October 2014

ABSTRACT

The usability of health information technology (IT) is increasingly recognized as critically important to the development of systems that are both safe to use and acceptable to end-users. The substantial complexity of organizations, work practice and physical environments within the healthcare sector influences the development and application of health IT. When health IT is introduced in local clinical work practices, potential patient safety hazards and insufficient support of work practices need to be examined. Qualitative methods, such as clinical simulation, may be used to evaluate new technology in correlation with the clinical context and to study the interaction between users, technology and work practice. Compared with the "classic" methods, such as heuristic inspection and usability testing, clinical simulation takes the clinical context into account.

This thesis sets out to examine how clinical simulation may be used in the various phases of the development life cycle of clinical information systems (CIS). The overall aim of my research is to investigate what might be gained from using clinical simulation in the development of CIS. Within this context, I will look into use of clinical simulation during the following phases; 1) requirement specification, 2) design, 3) procurement, and 4) organizational implementation and discuss opportunities and challenges involved in using clinical simulation.

To achieve this aim, an interpretive approach was employed. My research is interdisciplinary, integrating sociological and technological disciplines and is problem-driven using project-based teamwork. The research strategy is organized in three phases; 1) literature review, 2) five case studies, and 3) assessment of the opportunities and challenges involved in using clinical simulation. The case studies cover user requirement analysis and specification, design evaluation, a procurement process and application assessment in work. The methodological approach to my research is structured in an action learning cycle. In my research I apply field studies, contextual inquiry, interviews, workshops and clinical simulation. Data analysis is conducted by either instant data analysis or using a grounded theory-inspired inductive approach.

Clinical simulation can be useful in many processes in the human-centred design cycle. In the requirement specification, clinical simulation can be useful to analyze user requirements and work practice as well to evaluate requirements. In the design of health IT, clinical simulation can be used to evaluate CIS and serve as common ground to help to achieve a shared understanding between various communities of practice. In a public procurement process, a clinical simulation-based assessment can help give insight into different CIS solutions and how they support work practice. Before organizational implementation, clinical simulation is a very suitable means, by which to assess an application in connection with work practice.

The primary benefits of using clinical simulation are:

- involvement of users and clinical context
- controlled environments for experiments and formative evaluations of user satisfaction, usefulness and patient safety
- environments for addressing and visualizing cross-sectorial and cross-functional topics
- organizational learning space and common ground for gaining shared understanding.

The main concerns and challenges of using clinical simulation are:

- clinical simulation does not reflect the social-technical issues over time
- clinical simulation does not cover all possible work practice situations and issues
- to a great extent, the purpose and choice of scenarios determines the outcome.

The findings highlighted how clinical simulation can contribute to development of safe and useful CIS.

DANSK RESUME

Anvendeligheden af sundheds-it er i stigende grad anerkendt som værende yderst vigtig for udviklingen af systemer, for at sikre at systemerne er sikre at bruge og anvendelige for slutbrugerne. Den betydelige kompleksitet i både organisationer, arbejdspraksis og fysiske miljøer inden for sundhedssektoren påvirker udvikling og anvendelse af sundheds-it. Når sundheds-it er indført i lokal klinisk arbejdspraksis, bør potentielle patientsikkerhedsmæssige risici og utilstrækkelig støtte af arbejdspraksis afdækkes. Kvalitative metoder, såsom klinisk simulation, kan anvendes til at vurdere ny teknologi i sammenhæng med den kliniske kontekst, og til at studere samspillet mellem brugere, teknologi og arbejdspraksis. I modsætning til "klassiske" evalueringsmetoder, såsom heuristisk evaluering og usability test, tager klinisk simulation den kliniske kontekst med i betragtning.

Denne afhandling undersøger, hvordan klinisk simulation kan anvendes i forskellige livscyklusfaser i udviklingen af kliniske it-systemer. Det overordnede mål med min forskning er at undersøge, hvad der kan opnås ved at bruge klinisk simulation i udviklingen af kliniske it-systemer. Jeg vil undersøge brugen af klinisk simulation i de følgende faser; 1) kravspecificering, 2) design, 3) udbud, og 4) organisatorisk implementering samt diskutere muligheder og udfordringer ved anvendelse af klinisk simulation.

For at nå dette mål har jeg anvendt en fortolknings-orienteret tilgang, interpretivisme. Min forskning er tværfaglig og integrerer sociologiske og teknologiske discipliner. Den er problemorienteret og anvender projektbaseret teamwork. Min forskningsstrategi er inddelt i tre faser; 1) litteraturgennemgang, 2) fem case studier, og 3) vurdering af de muligheder og udfordringer, der er ved at anvende klinisk simulation. Casestudierne dækker brugeres analyse og specifikation af brugerkrav, formativ evaluering af design, offentligt udbud og vurdering af it-systemer i arbejdspraksis. Den metodiske tilgang til min forskning er struktureret i et aktion-læringsforløb. I min forskning anvender jeg feltstudier, interviews, workshops og klinisk simulation. Dataanalyse udføres ved brug af Instant Data Analysis og en tilgang inspireret af Grounded Theory.

Klinisk simulation kan være nyttig i mange processer i den menneskelig-centrerede design cyklus. I kravspecifikationen kan klinisk simulation være nyttigt til at analysere brugerkrav og arbejdspraksis samt til at evaluere brugerkrav. I design af sundheds-it kan klinisk simulation anvendes til at evaluere kliniske it-systemer, tjene som et fælles fundament og hermed bidrage til at opnå en fælles forståelse mellem forskellige praksisfællesskaber. I et udbud kan en simulationsbaseret vurdering hjælpe med at give indsigt i forskellige it-løsninger og hvordan de støtter arbejdspraksis. Før organisatorisk implementering er klinisk simulation velegnet til evaluering af it-understøttelsen af arbejdspraksis, patientsikkerheden og brugervenlighed i kliniske it-systemer.

De primære fordele ved at bruge klinisk simulation er:

- inddragelse af brugere og klinisk sammenhæng
- kontrolleret rum til eksperimenter og formative evalueringer af brugertilfredshed, nytteværdi og patientsikkerhed
- mulighed for afklaring og visualisering af tværsektorielle og tværgående dele af klinisk arbejdspraksis
- fælles udgangspunkt til opnåelse af fælles forståelse og organisatorisk læringsrum

De vigtigste problemer og udfordringer ved at bruge klinisk simulation er:

- klinisk simulation afspejler ikke de sociale-tekniske aspekter over tid
- alle situationer dækkes ikke af klinisk simulation
- formål og valg af scenarier bestemmer i stort omfang udfaldet af simulationerne.

Resultaterne af min forskning viser, hvornår og hvordan klinisk simulation kan bidrage til udviklingen af sikre og brugbare kliniske it-systemer.

ACKNOWLEDGEMENTS

This thesis would not been possible without economic and organizational support from CIMT, The Capital Region of Denmark; I owe special thanks to Niels Reichstein Larsen and Anna Chacon, without whom this thesis would never have been written. Thank you for believing in me and giving me a chance.

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Thanks to my colleagues at the ITX-lab, from whom I have benefited greatly during the case studies. Thank you for sharing your thoughts and experience. Special thanks to Stine Loft Rasmussen for many fruitful discussions and dialogs. I am grateful to all the participating clinicians as well as team members in the five project teams in the five case studies, who all willingly participated in simulations, observations and interviews.

I would also like to thank my co-authors for their kind cooperation in the publication process. Thanks also to Andre Kushniruk for making my three-month stay at the School of Health Informatics, University of Victoria (UVIC), BC, in spring 2013 both possible and productive.

Last but not least, thanks to Jan, my friends and my loving daughters, Signe and Rikke, for supporting me over the past three years.

TABLE OF CONTENTS

ABBREVIATIONS

ANT: Actor Network Theory

BO: Boundary Object

CIMT: Centre for IT, Medico and Telecommunications

CIS: Clinical Information Systems

COP: Community of Practice

COPD: Chronicle Obstructive Pulmonary Disease

CPG: Clinical Practice Guidelines

DM2: Diabetes Mellitus 2

EHR: Electronic Healthcare Record

GP: General Practitioner

IDA: Instant data analysis

ISO: International Organization for Standardization

IT: information technology

ITX: IT Experimentarium

RQ: Research Question

PCM: Planning and Coordination Module

PD: Participatory design

PPP: Public Procurement Process

STS: Science, Technology and Society

WoO: Wizard of Oz (for an explanation see page 32)

OUTPUTS ARISING FROM THE RESEARCH

Publications marked with "*" are part of my thesis. Unmarked publications are part of my research. All publications are peer-reviewed.

A. *Jensen S, Lyng KM, Nøhr C. The role of simulation in clinical information systems development. Stud Health Technol Inform 2012;180:373-7.

B. Rasmussen SL, Lyng KM, Jensen S. Achieving IT-supported standardized nursing documentation through participatory design. Stud Health Technol Inform 2012;180:1055-9. Best paper selection

C. *Jensen S, Vingtoft S, Nohr C. Benefits of a clinical planning and coordination module: a simulation study. Stud Health Technol Inform 2013;183:220-4.

D. *Jensen S, Nohr C, Rasmussen SL. Fidelity in clinical simulation: how low can you go? Stud Health Technol Inform 2013;194:147-53.

E. Rasmussen SL, Jensen S, Lyng KM. Clinical simulation as a boundary object in design of health IT-systems. Stud Health Technol Inform 2013;194:173-8. Jensen S, Rasmussen SL, Lyng KM. Use of clinical simulation for assessment in EHR-procurement: design of method. Stud Health Technol Inform 2013;192:576-80.

G. *Kushniruk A, Nohr C, Jensen S, Borycki EM. From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. Yearb Med Inform 2013;8(1):78-85.

H. *Jensen, S., Rasmussen, S. L., and Lyng, K. M., "Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms," Stud.Health Technol.Inform, Vol. 205, 2014, pp. 925-929.

I. *Jensen, S., Kushniruk, A. Boundary objects in clinical simulation and design of eHealth, Health Informatics Journal 2014

Articles under submission

J. * Jensen, S., Nøhr, C., Kushniruk, A. 2014. Clinical Simulation: A method for Development of Clinical Information Systems

K. * Jensen, S., Hermansen, B., Nøhr, C., 2014 Identification and prevention of Patient safety hazards

1 INTRODUCTION

This thesis deals with clinical simulation in relation to health IT in hospital settings. My research sets out to examine what might be gained from using clinical simulation in the development and evaluation of clinical information. I use the term *Development* in a broad sense. It includes all phases of the development life cycle of information systems, i.e. analysis, design and implementation until the system is operational. The term *Design* is used to describe the design phase, the term *Implementation* is used to describe the organizational implementation of an information system, and the term *Requirements* is used to describe user requirements unless otherwise stated.

Before summarizing my contributions, I wish to outline the structure of and background for the thesis.

1.1 SECTION OVERVIEW AND STRUCTURE OF THESIS

The thesis is structured in four parts; 1) Introduction, 2) Research Design, 3) Empirical Work and 4) Discussion, Conclusion and Perspective (See Figure 1). Part 1 is an introduction to my research, i.e. why it is of interest, my aims and my chosen approach and a literature review. Part 2 looks into the research design, i.e. theoretical approach, methods and description of case studies. Part 3 contains all my empirical work, including highlights from my publications structured in relation to my research questions. Part 4 is discussion, conclusions and perspectives in regards of my research.

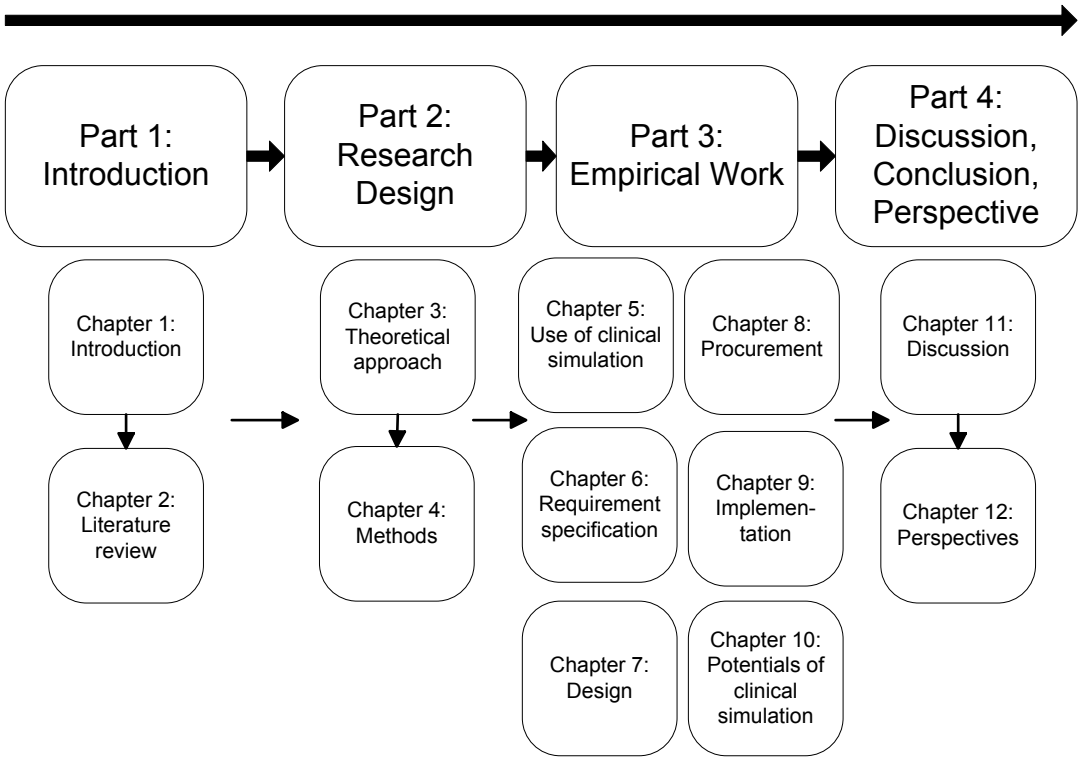


FIGURE 1 STRUCTURE OF THESIS

1.2 BACKGROUND – RESEARCH PROBLEM

Present-day health care meets increasing demands for efficiency in the form of high productivity and lower costs. Inadequate work flows may result in low efficiency and poor patient safety. Standardization of work and implementation of information technology (IT) are two methods used to optimize work flow and patient safety. However, patient safety in relation to health IT presents a paradox (1). Even though health IT may improve patient safety and quality (2), the application of new technology in healthcare may also increase patient safety hazards (3). Errors persist to occur in clinical practice even after new health IT has been introduced partly because manual processes co-exist with automated processes and the interfaces between the two seldom are perfect (4). Furthermore, new errors occur due to poor design of the information system (5; 6) and insufficient support of work flow (3). Studies show that adverse events in relation to new technology are more often related to the use of technology rather than to the technology itself (3; 6) and up to 70% of patient safety incidents are estimated to be related to or due to human factors (7).

Methods for design of eHealth focusing on patient safety are some of many initiatives trying to prevent adverse events (8; 9). Guidelines and standards (10-13) have been implemented that can address patient safety hazards in design of health IT. However, regulation and certification do not address safe use within the context of clinical work practice as this must be addressed locally in the organizations (14). Patient safety does not entirely rely on technology but is highly influenced by its interaction with users in a specific context (15). Socio-technical issues and human factors also exert an influence on unintended consequences and patient safety hazards (6; 8; 16).

The substantial complexity of organizations, work practices and physical environments within the healthcare sector impacts the development and application as well as the implementation and use of information systems (17; 18). Healthcare environments are profoundly collaborative and rely on coordination between various health professionals (19) and are characterized by delegated decision-making, multiple viewpoints and inconsistent and evolving knowledge bases (20). Multiple groups with potentially divergent values and objectives work together and face many contingencies which cannot be fully anticipated (21; 22). With staff-related variable, the difficulties complicate and challenges the wisdom of standardization in health care work (20).

When new technology is integrated in healthcare work practices, the implementation is difficult as it may not be possible to anticipate all actions and behaviors in a large socio-technical system (5). All possible interactions between the socio-technical system components are not predictable in the design phase and, in large complex systems, safety problems tend to emerge from unexpected interactions between the different components of a socio-technical system (13). Descriptions of work practices may be useful, but they are incomplete, summarized and rigid descriptions of modeled work practices, whereas specific work practices only unfold in their execution, in constant interaction with the context in which they are located (20).

When health IT is introduced in local clinical work practices, including existing and evolving technologies and organizational structures, possible patient safety hazards and insufficient support of work practices must be examined Evaluation of patient safety and new work flows in relation to use of technology in a clinical context is therefore highly relevant. However, most methods, such as field studies (3) and incident monitoring (13; 23), are retrospective and may therefore only be of limited use in the design and development of information systems.

Qualitative methods, including clinical simulation, have been used to proactively evaluate new technology in correlation with the clinical context throughout the software development life cycle in health informatics (24; 25), and to study the interaction between users and technology as well as the potential effects on clinical workflow and organizational issues (26; 27).

Compared with other methods, e.g. heuristic inspection and low fidelity usability evaluation, clinical simulation may have an advantage because, while other methods tend to focus merely on one or two aspects without the clinical context, clinical simulation takes the clinical context into account. Heuristic inspection focuses on the user interface and low fidelity usability testing focuses on technology and on the specific tasks of individual users. These methods may however complement clinical simulation by making a rigorous evaluation of the user interface and thus uncovering usability challenges in the graphical user interface. They do not, however, include the full clinical context and the interdisciplinary aspects of everyday clinical work.

Evaluation of clinical information systems (CIS) based on clinical simulation may allow for a high degree of experimental control and still allow maintenance of a high degree of realism with regard to the clinical context (28). Clinical simulation studies have proven feasible for conducting safe evaluations of technology before it is introduced into routine clinical practice (29). Clinical simulation has also been used to evaluate the potential impact (30), cognitive processes and usability (25), and work practice (27). Patient safety issues are difficult to evaluate due to the fact that many patient safety challenges lie in the details and are triggered by an adverse event and work-related interruptions. It is often difficult, sometimes almost impossible, to pinpoint these challenges in advance. They must instead be explored when a new technology e.g. an information system is to be applied. Notwithstanding the above, clinical simulation may be an appropriate method by which to assess patient safety aspects as it provides a comprehensive view of the information system taking into account the correlation between IT, work practice and adverse events (31).

One of the challenges in designing information systems is identifying user requirements. Lucy Suchman cites David Well in an article about making work visible: "*How people work is one of the best kept secrets in America*" (32). She describes how work may be invisible for others and how work may be interpreted differently. According to Suchman, work descriptions do not reveal all aspects of work processes and work practices. The more enhanced the work is done, the more difficult it is to see. Knowledge arises as much from interaction as from evidence. "*You can't write all you say, you can't say all that you know, you often don't know what you know until you need to, you often know how to find who does know*".

Needs and requirements differ throughout an organization and development is an important issue in off-the-shelf CIS products (20). Such products require extensive tailoring and configuration to match local requirements and context. Many different views need to be taken into account in the development and retailoring, and a shared understanding between the different stakeholders is imperative. Furthermore, communication between end-users and developers is often challenging and dialog and discussions with a view to finding common ground is often needed to bridge the gap between the parties (33).

Since 2007 clinical simulation has been used in the Capital Region of Denmark to evaluate CIS. Since 2011, it has been mandatory ahead of the implementation of CIS at the regional hospitals. As elsewhere (5; 34-36), for many years the region had found implementations challenging, due to e.g. lack of sufficient ability to support and cooperate with the clinical work processes and user interfaces that were not user-friendly. The unintended results were many, e.g. work-

arounds, misuse of information systems, adverse events and disillusioned user, and the need to assess usability and effectiveness of CIS in a clinical context emerged. For this reason, the IT Experimentarium (ITX) was established (37). The purpose of ITX was to evaluate CIS using clinical simulation. The aim was to assess new technology in clinical practice and analyse existing and new work practices.

The resources invested in preparing and performing simulation studies are often exhaustive, depending on the required degree of fidelity, and it is essential that the resources invested in creating a realistic setting match the purposes of the evaluation and the simulation set-up (30; 38). However, the resources saved by using clinical simulation for analysis and evaluation purposes are difficult to quantity as it is difficult to put a price on the value of patients' lives.

One of medicine's moral dilemmas is that of putting today's patients at risk in order to train tomorrow's practitioners. Medical simulation has been used in connection with clinical skills training and the social-team-oriented and cognitive-individual-oriented aspects of clinical work practice for more than four decades, thereby reducing the need for unskilled practicing on patients and the risk of safety hazards (39-47). Similarly, clinical simulation is expected to become a beneficial method by which to evaluate CIS, as simulations can take place in a controlled environment where there is no risk of injuring real patients (48; 49).

Research concerning simulation in the training of healthcare professionals is comprehensive (39; 41-43; 46; 47). On the other hand, there has been no thorough research of clinical simulation in relation to design and evaluation of CIS. This thesis addresses how clinical simulation may be used in different stages of the life cycle of CIS to improve the use and outcome of the systems.

1.3 RESEARCH AIMS & OBJECTIVES

The aim of this PhD study is to develop, apply and evaluate methods for using clinical simulation at the different phases in the life cycle of information systems. My approach is to review the literature and several case studies covering various phases in the development life cycle. In the case studies, I investigated the benefits and limitations of clinical simulation and focused on how and for what purposes clinical simulation can be used. The case studies covered various phases in the CIS development life cycle.

The overall aim of my research is to investigate what might be gained from using clinical simulation in the development of clinical information systems. The PhD study investigates the significance of using clinical simulation in the development and evaluation of CIS and discusses the opportunities and potential benefits, challenges and limitations of using clinical simulation. The research questions (RQ) are described in the next section along with a short description of the topic, objectives and methodology used to investigate each question, and the papers related to each of the research questions.

1.3.1 RESEARCH QUESTIONS, OBJECTIVES AND METHODOLOGY

The primary research question this thesis sets out to examine was:

RQ 0: What might be gained from using clinical simulation during various phases in the development of clinical information systems?

Within the context of the primary RQ, the research had the following secondary RQs:

- ***RQ1 - How can clinical simulation be used in the development and evaluation of clinical information systems?***

  Topic: A description of how clinical simulation can be conducted, and the pros and cons highlighting steps towards successful simulation.

  Objective: To describe a method for planning, preparing and conducting clinical simulation, taking into account the opportunities, benefits, challenges and limitations of the method.

  Methodology: Developed out of the experiences from 25 studies performed in the period 2007 till 2014, in which clinical simulation was used to support the design, evaluation and optimization of CIS before implementation in real practice. A scientific simulation study of a prototype of a planning and coordination module was used as a recurring example. Some of the unintended consequences and benefits discovered during the evaluations were discussed. Finally, key issues in the form of steps required in order to make a successful simulation were highlighted.

  Publication: "J: *Clinical simulation: A method for Development of Clinical Information Systems*, Jensen, S., Nøhr, C., Kushniruk, A., 2014".

- ***RQ2 - What are the potentials of using clinical simulation in specification of user requirements for clinical information systems?***

  Topic: How can clinical simulation support understanding and specifying the context of use, and user and organizational requirements?

  Objectives: One paper presented a clinical simulation study, the purpose of which was to analyze user requirements for an Electronic Health Record (EHR) platform in close collaboration with end-users and their simulated daily work practice. Another paper demonstrated a formative evaluation of a cross-sectorial planning and coordination module in relation to requirement specification.

  Methodology: Two different approaches were chosen. In the first simulation study, cardboard boxes and post-it labels were used as low-fidelity mock-ups to analyze user requirements. The need for fidelity was subsequently matched up to four different fidelity dimensions. In the second study, a high-fidelity prototype was evaluated. The prototype design was based on requirements analyzed and specified by end-users, health informaticians, etc.

  Publications:

  "D: *Fidelity in clinical simulation: how low can you go*?, Jensen S, Nøhr C, Rasmussen SL,. 2013",

  "C: *Benefits of a clinical planning and coordination module: a simulation study*, Jensen S, Vingtoft S, Nøhr C., 2013".

- ***RQ3 - What are the potentials of using clinical simulation in design of clinical information systems?***

  Topic: How can clinical simulation improve the design of CIS and how can clinical simulation be used to acquire a shared understanding and common ground for discussions between the stakeholders (e.g. end-users, risk managers, quality managers and clinical management) representing dispense goals for and views on applicability and implementation of new technology?

  Objectives: The paper focused on use of clinical simulation as part of the participatory design approach and discusses the use of clinical simulation as a boundary object to translate, transfer and transform knowledge between various communities of practice (COP) in healthcare organizations.

  Methodology: A scientific case study was used to investigate how clinical simulation can act as a boundary object in a participatory design process and support stakeholders in a large healthcare organization to achieve a mutual understanding of the different domains each stakeholder represents. The application used in the study was clinical documentation templates for initial nursing assessment.

  Publication: "I: *Boundary objects in clinical simulation and design of eHealth*, Jensen, S., Kushniruk, A., 2014".

- ***RQ4 - What are the potentials of using clinical simulation in assessment of clinical information systems as part of a procurement process?***

  Topic: The cognitive aspects influencing clinical work practice in relation to any particular system are difficult to assess using quantitative methods. How may clinical simulation be used in connection with procurement?

  Objective: To develop, use and evaluate a method by which to assess qualitative aspects of user satisfaction, usefulness and patient safety. The method should cover demands from various end-users, medical specialties, and cultures, and meet demands for transparency in connection with public tender procurement in accordance with EU regulations.

  Methodology: A method for using clinical simulation to assess qualitative aspects, such as human factors and usability of three different EHR-platforms, was developed, used and evaluated in connection with the process to procure a large EHR platform. The method actively involved clinicians in the public procurement process. The method was evaluated by describing three aspects of the human factor issues that the method was designed to cover; 1) user satisfaction, 2) usefulness and 3) patient safety.

  Publication: "H: *Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms*, Jensen, S., Rasmussen, S. L., and Lyng, K. M., 2014".

- ***RQ5 - What are the potentials of using clinical simulation to acquire knowledge of implementation?***

  Topic: How can clinical simulation support the acquisition of knowledge regarding aspects of implementation, such as patient safety hazards and work practice?

Objective: To assess the potential of applying clinical simulation as a proactive method to identify and evaluate potential patient safety hazards and support of work practice prior to implementation.

Methodology: A case study investigated how a standardized information system "OPUS Inbox" supported clinical practice, and identified potential patient safety hazards and how work practice was supported prior to implementation.

Publication: "K: *Identification and prevention of Patient safety hazards*, Jensen, S., Hermansen, B., Nøhr, C., 2014".

1.4 RESEARCH APPROACH

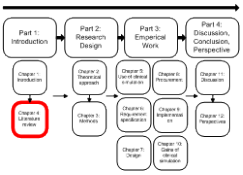
The PhD study encompassed a literature study and five case studies covering various phases of the life cycle of a CIS. For a full description of the five case studies, see section 3.2.1. The usefulness of and challenges involved in using clinical simulation in the design and evaluation of CIS was investigated in these studies. The research approach was interdisciplinary, integrating sociological and technological disciplines. The approach was also problem-driven using project-based teamwork. The study was essentially a "hybrid imagination" combining human and sociological sciences with more technical competences from IT development (50).

The degree to which I was involved in my studies was a professional challenge. On the one hand, I had to achieve and sustain academic distance. On the other hand, I offered advice on issues and had to avoid getting involved. My role as a researcher was participatory. I participated in the research as a facilitator giving advice and, at the same time, I was the manager, maintaining an overview. I observed and sought to achieve a valid, plausible and reflexive understanding of the meanings ascribed by the participants during the case studies.

My research drew on elements from various scientific approaches and combined them throughout the study without applying a predetermined theory chosen for abstract and theoretical reasons alone. I approached the subject matter cautiously and decided, along the way, which theories would best serve my purpose. My approach was explorative and embraced an iterative process. Contrary to a waterfall design process (51), my approach harmonized well with the iterative life cycle approach in user-centred design (52). The first part of my thesis focused on acquiring broad knowledge of the current research status and position worldwide regarding the use of simulation with real users in designing and evaluating CIS. The second part focused on applying this knowledge in practice in five case studies. The overall scientific approach was participatory research.

The practice of science was creative, using experimental methods of discovery, instrumental rationality and a search for workable tools and instruments. The study was empirical with emphasis on observation and data collection. Through the study I have searched for insight and for theories that can be practically applied. The project was mixed method research with a preference for quantitative methods, where I combined phenomenological approaches (observations) with hermeneutic elements in an attempt to understand the users through interviews with them.

This section has outlined the background for my research. I have presented my research aims and objectives as well as my research approach and my own relevant publications. The next section will give an overview of the experience of using clinical simulation.



2 LITERATURE REVIEW

This section is based on the two publications 1) A: The role of simulation in clinical information systems development (53), and 2) G: From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. (48). The first paper is a literature review and the second is an exploration of human factor approaches to understanding the use of health information technology by extending usability approaches to include analysis of impact of clinical context through the use of clinical simulation.

The strategy of the literature review was to conduct a systematic review and making an exhaustive summary of current literature relevant to my research question. There are several standards and guidelines for conducting a systematic review. This review, as presented in Figure 2, selected the most relevant components following the PRISMA 2009 flow diagram (54).

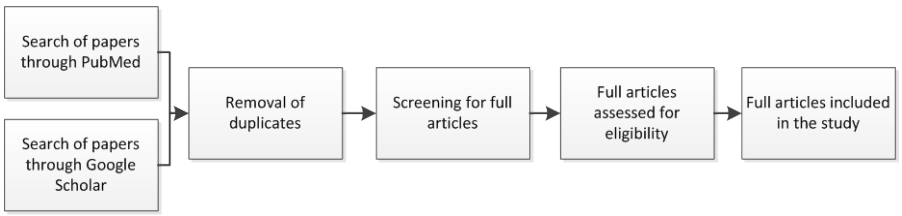


FIGURE 2 LITERATURE REVIEW

The first step was to identify potential literature. The PubMed database was searched using the following MeSH Terms: Computer Simulation(s) OR Humans OR User-Computer Interface(s) OR Medical/clinical Informatics AND date after 1990 AND language: English. The search was extended for all fields with: simulation OR fidelity AND clinical information system. Google scholar was searched with additional terms: Fidelity, full-scale simulation, clinical information systems, usability testing and evaluation. Only papers in English and written after 1990 were included. The relevance of each publication was examined by reading of the abstract. The search was carried out in December 2011.

A total of 1,161 papers was found. Duplicates and papers for which a full paper was not accessible were excluded. Most of the remaining literature concerned medical simulation used in the training of healthcare professionals. Medical simulation for training has been used in the last four decades as opposed to clinical simulation used for evaluation of CIS, which has only been used for just over a decade. The proportion of papers concerning simulation in relation to development and evaluation of CIS was therefore quite small. Based on the extent to which end-users were involved in the simulations and on how they presented new knowledge about simulation in relation to the design, development and application of CIS, a total of 29 papers concerning simulation were seen to be highly relevant for this review.

Simulation may be conducted with (48) or without end-users (55), or as a hybrid, where simulation with end-users is combined with computer-based simulations (56). Simulations with real users focus on the "*human-in the-loop*" (25) as opposed to computer-based simulations focusing on the "*computer-in-the-box*" (55). This literature review was focusing on clinical simulation where real users are enacting realistic clinical work scenarios.

The literature review disclosed that simulation has been used at various stages of the life cycle of CIS; from the specification of requirements to the actual implementation and maintenance of the system. Simulation has been used to evaluate a wide range of CIS (57; 58). In contrast to field studies, simulation studies allow for the possibility of examining a variety of complex and extreme usage scenarios during a short but highly intense test phase (59). Simulation methods have been used in biomedical informatics to study various aspects of human computer interaction in a number of research domains, including human factors, usability, doctor-patient interaction involving technology, health professional information requirements, health professional decision-making, new device testing and studies of medical errors (25; 27; 55; 59).

In the early phases of the CIS life cycle, simulation has been used to analyze user requirements using prototypes or storyboards in preliminary tests (25). Simulation has also been used to obtain and assess knowledge of user work practice (27). In the design phase, simulation has been used as a method by which to involve users and provide iterative feedback for the design of prototypes or real systems (25). The benefit of simulation studies is that they can be designed to study practical experience in the design process of new technology without introducing ethical issues or putting patients at risk. The aim of simulation studies in the design phase is to create design proposals for a new technology and may combine elements of laboratory testing and field study (29).

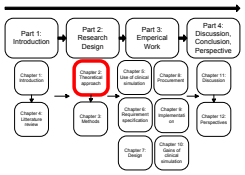
In the implementation phase, specific aspects of implementation has been visualized through simulation, e.g. user interaction in work practice, the need for training, and the impact of decision support (60). Unintended consequences of new systems, such as changes in work processes and patient outcomes may be detected and can provide organizational decision- makers, if necessary, with an opportunity to correct actions (27).

For simulations to work efficiently, it is important to define the purpose and identify an adequate level of simulation fidelity. Simulations can be adjusted to address specific issues by making participants to focus on fixed aspects. With an adequate degree of realism, evaluators can address how various elements may affect the simulated work practice and use of CIS (61).

The literature revealed that clinical simulation may be well suited for assessing work practice and human factors and should play a substantial role in the design, development and implementation of CIS. Simulation studies may be a very relevant method for evaluating CIS throughout the life cycle and provide essential feedback for continuous progress in each phase. Simulation studies may be useful for defining user requirements and analyzing work practices from the initial phases of CIS. Simulation can subsequently be used in the design and development of CIS as well as in implementation planning. By using simulations, healthcare organizations may effectively identify issues that could potentially arise from the introduction of new technology prior to their introduction in real-world settings.

The literature review did not reveal any studies containing a thorough methodological description of how clinical simulation is conducted or how fidelity influences the outcome of a simulation study. The review revealed no case studies on how clinical simulation may be used in relation to procurement. The reviewed literature indicated that correctly performed simulation studies can be an efficient method by which to prevent late system failures and may improve patient safety significantly. Further research is required to prove this.

This section has provided an overview of existing literature and experiences of using clinical simulation. The review indicated that clinical simulation is an extensive practice and suggests areas for further research. The next section describes the theoretical approach I adopted in order to achieve my research aims.



3 THEORETICAL APPROACH

This thesis investigated how and for what purposes clinical simulation can be used in the development of CIS. Little is known about these issues and the health informatics literature on simulation tends to focus on clinical simulation applied to summative evaluation. There is a need for a more sophisticated approach to evaluate the potential for using clinical simulation not only in formative and summative evaluation of CIS, but also in analyzing and investigating the effects of CIS in the clinical context and work practice.

My theoretical approach has been explorative. I sought to acquire an understanding rather than to explain. Quantitative methods seek proof and explanations focusing on summary characterizations and statistical explanations, while qualitative methods attempt to comprehend, by offering complex descriptions to explain webs of meaning (62). Kvale describes two different scientific approaches symbolized by a miner and a traveler (63). The miner represents a positivistic approach, while the traveler's is an interpretive or constructive approach. The miner believes that knowledge is buried in the ground; he only has to dig for it. The traveler sees the world as a social construction, which can only be understood in a dialog with those who live in it. As my research approach is explorative and cognitive, I perceive myself as the traveler, primarily taking an interpretive approach. According to Walshman (64), interpretive methods of research assume that our knowledge of reality is a social construction with human actors, (in the present context, researchers). There is no objective reality, which can be discovered and replicated by others.

3.1 RESEARCH PHILOSOPHY

Before initiating any research, the researcher must consider his or her fundamental philosophy regarding the nature of reality, knowledge and human behavior as these philosophies influence ontology, epistemology and the choice of methods appropriate for the research (65). In my research, a subjective ontology utilizing an interpretative epistemology was embraced. According to an interpretive view, reality is socially constructed and never objectively and unproblematically knowable. As a researcher, the identity and values of the interpretive approach are inevitably implicated in the research process (66). An interpretive researcher seeks a valid, plausible and reflexive understanding of the meanings ascribed by the actors. The aim of interpretive research according to a interpretivistic philosophy is to understand and reconstruct (65). Methodological choices are primarily hermeneutic, dialectic and phenomenological.

As my research sought to investigate how clinical simulation can be used to acquire knowledge about the correlation between technology, organization and human beings, it was important to focus on the attitudes, insights and experiences of the individuals involved. I conducted my research within a subjective interpretative paradigm which did not impose constraints on my data collection methods and analysis techniques. Interpretive methodology includes qualitative, naturalistic and pluralistic methods, where the data is analyzed for meanings and perspectives. Pluralistic methods are multiple methods preferred to give a rich picture of reality.

My research may be seen as a type of "hybrid imagination". A hybrid imagination can be defined as "the combination of scientific-technical problem-solving with an understanding of the problems that need to be solved" (50) p4. It blends scientific knowledge with technical skills and reflects the cultural implications of science and technology in general and the scientist's or engineer's own contribution. A hybrid imagination is often manifested collectively, involving collaboration between two or more people. The context of knowledge creation is transformed from disciplinary, through multidisciplinary and interdisciplinary to trans-disciplinary. Current research tends to be trans-disciplinary(50). My research tends also to be trans-disciplinary, as it looks into the fields of technology, health care and social science.

3.1.1 THE ONTOLOGY

Ontology is the theory or study of existence and refers to the perceived nature of the world around us. Ontology examines whether the empirical world is objective, independent of humans or subjective, having existence through the action of humans and recreating it (67). Ontology is prior to and subsequently governs epistemological and methodological assumptions (68).

A subjective ontological view can be described as a view which emphasizes the subjective behavior or reasoning that determines how people construct their own reality within the constraints of society's agency (67). This view implies that the researcher assumes that the social world is created and reinforced by humans through their actions and interactions. An interpretive research scientist assumes that there are multiple realities, socially constructed through symbolic interactionism, framing and sense-making (66). In other words there is no single truth but multiple truths, the world is changeable and viewed through a social psychological perspective and reality depends on time, place and context.

In order to get a profound insight into the potential of using clinical simulation, I embraced a research philosophy that uses a subjective ontological approach (67). On the basis of the research questions propounded in this study, I employed interpretive epistemology to engage with the participants in the case studies in order to gain deep insight into how and for what purposes clinical simulation may be used.

Given that the research seeks to examine how clinical simulation may be used to acquire knowledge about the relationship between clinicians, organization and technology, it was relevant to focus on the influence of technology on users (healthcare professionals) and on the organization, and, equally, to focus on the influence exerted by users and the organization on technology through e.g. the creative use of technology, new requirements and further development.

According to the socio-technical approach, work practice is conceptualized as "networks of people, tools, organizational routines and documents" (20) (p. 87). The social perspective views social aspects (information system, equipment and tools) as interdependent entities which require equal consideration when understanding work environments (21). The social and technical aspects must be considered, independently and interdependently, as optimization of the one may have a negative impact on the other. There is a need for dual focus and joint optimization (69). The socio-technical systems model views organizations as transformation agencies, which transform inputs into outputs (70). Socio-technical systems grasp three major elements in this transformation process: a technological subsystem, a personnel subsystem and a work system design covering the organization's structure and processes. These three elements interact with each other and with the external environment.

From the perspectives of symbolic interactionism focus on the actions of the actors, interaction between the actors, and the relation and integration with objects, are especially relevant. How do actors perceive, adapt and react in relation to other actors? These issues are very important to the design and evaluation of IT systems and we focus on them during clinical simulations and observations. Issues related to visible and invisible knowledge and behaviors, with which Strauss and Star have worked, are essential aspects of the development and evaluation of information systems (71; 72).

Symbolic interactionism considers meanings to be *social products*, i.e. creations that are formed and transformed in and through the defining activities of actors as they interact (73). When actors deal with the world of their objects and act in relation to it, creation and refinement of meanings might result. To understand the actions of people, it may be best to understand the worlds of their objects. Meaning thus created may be provisionally externalized through symbolic representations and concrete artifacts. Sometimes the same objects may appear in different worlds, which leads to a flexible interpretation and thereby a possible coordination between the actors of the different worlds. These objects are called boundary objects.

Star and Griesemer (74) define boundary objects as "*flexible epistemic artefacts that inhabit several intersecting social worlds and satisfy the information requirements of them". "They have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable, a means of translation*" (p393). Objects become boundary objects when they are used at the interface of different communities of practice. A community of practice has a shared understanding of what the community does, of how it does it, and of how it relates to other communities and their practices, and will develop the same world view or mental model (75). Boundary objects may be physical objects as well as symbolic objects. They are a kind of socio-technical hybrid spanning across boundaries of different worlds enabling and constraining knowledge sharing across boundaries (76) carrying information and context that may be used in translating, transferring and transforming knowledge between communities of practice (77). Boundary objects may be a sort of arrangement that allows different groups to work together without consensus, something people act against, towards, and with (78). Boundary objects may be repositories (e.g. a library or a database), ideal types (e.g. a diagram or a roadmap), coincident boundaries (e.g. the boundaries of a state) and standardized forms (e.g. classifications) (74). Technology may be considered a boundary object that can induce transformational learning in practices related to integrated design (79).

Boundary objects may be used to achieve a shared understanding of collaborative processes in the development of future collaborative processes and products (80) and as a framework for modeling and categorizing organizational interfaces (81). Boundary objects are frequently seen in eHealth, e.g. in clinical documentation and classification (82; 83). They involve the participation of actors from both sides of the boundary with professionals, who serve as mediators, and they exist at the border of two somewhat different social worlds, but there are distinct lines of accountability to each of them.

3.1.2 THE EPISTEMOLOGY

The term "epistemology" refers to beliefs and assumptions about the way in which knowledge is acquired and constructed (84). These beliefs relate to how one might understand the world and communicate this to others (85). Humans establish knowledge through negotiations, common beliefs, experience and tradition. According to an interpretive view, knowledge is subjective, context-dependent, value-laden and emerges from researcher-participant interaction (66).

My study was explorative and the data was rich and contextual. The data had to be analyzed for meanings and perspectives, although the aim was not to strive for absolute objectivity and testability. Values, such as credibility, conformability and transferability, were embraced instead (63; 65). Brannen (86) suggests that the choice of methods and how they are used is likely to be informed by the research questions. According to Pope (87), qualitative research deals with speech and words, and answers questions such as "what is?" and "how does?". Qualitative research is "*concerned with the meanings people attach to their experiences of the social world and how they make sense of that world*" (87) p4. Qualitative research attempts to interpret social phenomena, such as interactions and behaviors, in terms of the meanings people bring to them and seeks to answer fundamental and searching questions about social phenomena. According to Gadamar (88), pre-understanding will always set the conditions for understanding. Pre-understanding includes everything we know or think we know. Pre-understanding is always present and often unnoticed. On the other hand, Gadamer states that, without some kind of pre-understanding, it is difficult to ask questions. In hermeneutic philosophy, generality is not viable because it is not possible to preclude the context (89). Generality becomes rather a matter of transferability of the interpretations to other situations, and receptiveness, sensitiveness and uprightness are embraced. Quality in knowledge is assessed and accepted inside the field of science rather than focusing on validity as would be the case when using a more positivistic approach. Kvale (63) introduces analytical generality as a considered assessment of the degree to which the results of one study may be instructive as to what might happen in the next study based on an analysis of similarities and differences.

I embraced an interpretive research approach as a way of obtaining knowledge about what may be gained from using clinical simulation and how. An interpretive approach is based on an ontology in which reality is subjective, a social product constructed and interpreted by humans as social actors according to their beliefs (90). In interpretative research the researcher does not construct a social setting before entering it, but allows constructs to emerge while the researcher is in the field, acquiring knowledge and trying to understand a phenomenon. The use of interpretive epistemology makes it possible to understand phenomena by accessing the meanings given to them (67). Using an open-ended, qualitative, subjective approach in my research, it was possible to obtain profound knowledge and an understanding of what might be gained from using clinical simulation, and what the possible challenges, limitations and potential disadvantages might be.

The research philosophy I adopted enabled me to consider the participants' subjective experience in the case studies and to embrace openness, with a subjective ontological position and an interpretive epistemology.

3.2 RESEARCH STRATEGY

The research strategy employed to collect information was organized in three main parts and relied upon the use of:

1) Literature review: Gathering of national and international experiences through literature study following a PRISMA approach (54)
2) Case studies: Five case studies were conducted using clinical simulation for development and evaluation of clinical information system during various phases in the life cycle of CIS, i.e. analysis and specification of user requirements, design, procurement and implementation
3) Assessment of the potential of and challenges in using clinical simulation during the life cycle of a clinical information system from the very early stages until implementation

I chose a qualitative research design as the most suitable design for the exploratory nature of this study. In qualitative research, theoretical orientation enables the researcher to adopt a flexible approach to the observed reality and offers concepts to explain the phenomena. The researcher is able to move beyond basic description to in-depth description, interpretation and explanation (91). I chose multiple qualitative methods in order to create a rich picture. Subsequently data was analyzed for meanings and perspectives. I do not intend my study to verify a hypothesis but aimed to describe, analyze and interpret how and for what clinical simulation may be used during the various phases of the life cycle of CIS. I chose therefore a case-based approach where cases with different characteristics and from different phases in the life cycle of CIS were applied.

3.2.1 CASE STUDIES

Context-dependent experience and knowledge are at the very heart of expert activity and lie at the core of any case study as a research method for learning (92). Case studies are especially appropriate to use in producing concrete, context-independent knowledge. Case studies produce rich insights and are very suitable for exploring "how" and "why" questions (93) which validates an interpretive approach. The advantages of case study research strategies include facilitating the study of a phenomenon in a natural context, and of a large number of issues and different aspects related to the phenomena.

According to Flyvbjerg (92) "*One can often generalize on the basis of a single case, and the case study may be central to scientific development via generalization as supplement or alternative to other methods. But formal generalization is overvalued as a source of scientific development, whereas 'the force of example' is underestimated*". The aim of my research was not to generalize. It was instead to obtain knowledge in order to investigate how clinical simulation may be used and what might be gained from using clinical simulation. Even though, generalizability can be increased by the strategic selection of cases. The greatest possible amount of information about a given problem or phenomenon may not be achieved through a representative case or a random sample (92). Flyvbjerg argues that atypical or extreme cases often reveal more information because they activate more actors and more basic mechanisms.

From an understanding-oriented and acting-oriented perspective, it is often more important to clarify the deeper causes behind a given problem and its consequences than to describe symptoms and frequency. Extreme cases are suitable for emphasizing a point in a particularly dramatic way. Meanwhile, critical cases have strategic importance in relation to general issues, e.g. the requirement analysis, where cardboard boxes represented computers and a person using post-it labels acted as the information system, or in the procurement study which had to meet the demands for uniformity and transparency in a public procurement process. Paradigmatic cases are suitable for developing metaphors or establishing a school for a domain. The studies concerning design and implementation were both typical cases with frequently used purposes. The strategies are not necessarily mutually exclusive. A case might be extreme, critical and paradigmatic at the same time because it provides several perspectives and conclusions on the case depending on whether it is viewed and interpreted as one or the other type of case. Contrary to a random selection of cases, an information-oriented selection maximizes the utility of information from single cases and small samples, where the selection is based on the expectations of their information content.

3.2.2 DESIGNING HUMAN TECHNOLOGIES

My research has focused on the development and evaluation of clinical hospital information systems. Health informatics researchers and professionals, amongst others, have argued that, of all work domains, healthcare is the most challenging, given the variety, range and complexity of situations and settings in which healthcare information systems are deployed (94). Healthcare is generally a complex area, and hospital organizations and work practice are particularly complicated as there are many different healthcare groups and many interactions and correlations (34) involved, and many acute situations are encountered during daily work practice in hospital settings (95). This complexity affects the technology that is developed and implemented at hospitals (5) and confronts the methodology used for developing and evaluating healthcare information systems. Failure to comprehend the nature and range of end-users has been highlighted as a key issue in many systems' failing to become accepted by healthcare professionals (96). Furthermore, an understanding of the context in which the systems will be used must take into account not only tasks and settings (97), but also the range, competences and cognitive capacities of an increasing variety of potential end-users (98). The risk of endangering patient security calls for careful evaluation before implementing new technology in real life settings (99). These evaluations may be conducted in realistic (high fidelity) environments, i.e. close to real life (30). In this section, I will describe the most significant aspects used in designing human technologies.

Usability may be defined as in ISO 9241: "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"(100), although other definitions exist (101; 102). According to ISO 9241, *effectiveness* is defined as "accuracy and completeness with which users achieve specified goals", *efficiency* is defined as "resources expended in relation to the accuracy and completeness with which users achieve goals", *satisfaction* is defined as "freedom from discomfort, and positive attitudes towards the use of the product", and *context* is defined as "'users, tasks, equipment (hardware, software and materials), and the physical and social environment in which a product is used". In this thesis the ISO definition are used as a basis for describing usability.

There remain, however, some unanswered questions as to who the users are. Damoran (103) describes two levels of users, 1) end-users who interact directly with the information system to perform their work, and 2) users who utilize printouts or manage end-users. Conventional usability testing profiles and targets prescribe groups of users (104), whereas the healthcare sector poses challenges due to the larger potential numbers and classes of users, e.g. nurses, physicians and pharmacists (96). Each class of users may contain subclasses, such as emerging physicians, attending physicians and surgeons (105). Demographic differences, such as e.g. gender, age and computer literacy, have to be considered as well (106). In addition, the complexity of environments and tasks carried out by various types of users makes it a difficult to profile and target prescribed groups of users in healthcare (107). Furthermore, the ISO standard does not take several users and their professional interaction into account, and nor does it take parts of or a whole organization into account. Healthcare environments are profoundly collaborative and rely heavily on coordination between different healthcare professionals (19).

Hertzum points out that many views may be put on usability even though the definition is fixed (108). Hertzum divides usability into six images:

- *Universal usability*: usability in a system for everybody to use
- *Situational usability*: usability is equivalent to the quality-in-use of a system in a specified situation with its users, tasks, and wider context of use

- *Perceived usability:* usability concerns the user's subjective experience of a system based on her or his interaction with it
- *Hedonic usability:* usability is about joy of use rather than ease of use, task accomplishment, and freedom of discomfort
- *Organizational usability:* usability implies groups of people collaborating in an organizational setting
- *Cultural usability:* usability takes on different meaning depending on the users different background

Universal usability may relate to log-on, change of passwords etc. but most parts of CIS are not meant to be universal. Situational usability takes the context and collaboration between several users into account, which is highly relevant in healthcare. Perceived usability is more user-centered than usage-centered and strong focus on perceived usability may fail to recognize organizational and other contextual factors. Hedonic usability is mostly relevant in relation to consumer products and games. Organizational usability is highly relevant in complex organizational settings such as healthcare. Three elements are consistently important in health IT: common ground between collaborators (109; 110), awareness of the evolving state of collaborate work between healthcare professionals (111; 112), and coordination of healthcare activities (113; 114). Cultural usability is relevant in relation to e.g. the differences in educational, professional and speciality backgrounds among healthcare professionals (95).

<u>*Human factors*</u>

According to the International Ergonomics Association, human factors or ergonomics can be defined as "[] *the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance*" (115). The system represents the physical, cognitive and organizational artifacts that people interact with and can be a technology, software or medical device; a person, team or organization; a procedure, policy or guideline; or a physical environment. Ergonomics focuses on the design of systems to fit the requirements, capacities and limitations of users (116). The discipline of human factors can contribute to safe design of healthcare systems by considering the various requirements, capacities and limitations of users (117), and the quality and safety of care is influenced by various characteristics of the system(118). The discipline of human factors and ergonomics covers three main domains: 1) physical ergonomics concerned with physical activities, 2) cognitive ergonomics concerned with cognitive processes, and 3) organizational ergonomics (or macro ergonomics) concerned with socio-technical system design (116). Hendricks describes five "human-system interface technologies" of the human factor and ergonomics disciplines (119-122): 1) human-machine interface technology, i.e. hardware ergonomics, 2) human-environment interface technology, i.e. environmental ergonomics, 3) human-software interface technology, i.e. cognitive ergonomics, 4) human-job interface technology, i.e. work design ergonomics, 5) human-organization interface technology, i.e. macro ergonomics.

<u>*User-centered design*</u> focuses on incorporating the user's perspective into the development process in order to attain a usable IT system(123). The key principles of user-centered design are 1) active involvement of users and clear understanding of user and task requirements, 2) an appropriate allocation of function between user and system, 3) iteration of design solutions, and 4) multi-disciplinary design teams. The ISO standard 9241-210:2010 Ergonomics of human-system interaction Part 210: Human-centred design for interactive systems (52) describes five essential processes which should be undertaken in order to incorporate usability requirements into the software development process. Figure 3 shows the human-centred design cycle according to the

ISO standard. As shown in Figure 3, the process is iterative with the cycle being repeated until the particular usability objectives have been obtained.

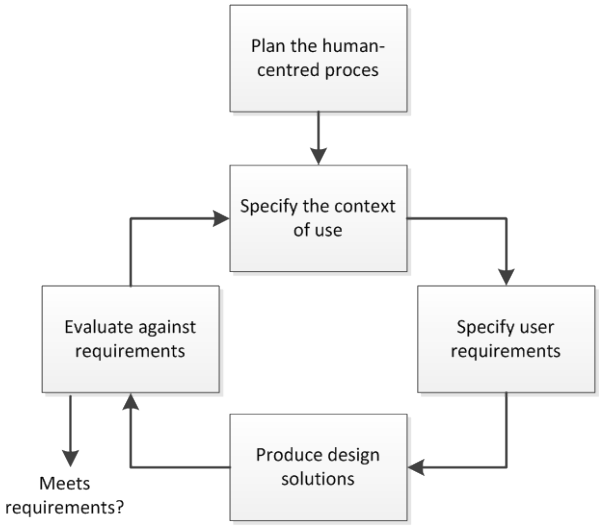


FIGURE 3 THE HUMAN-CENTRED DESIGN CYCLE

Studies show (103; 124) that effective involvement of users may lead to 1) improved quality of the system arising from more accurate user requirements, 2) avoidance of costly system features that user do not want or cannot use, 3) improved levels of acceptance of the system, 4) greater understanding of the system by the user resulting in more effective use, and 5) increased participation in decision-making in the organization. Forms of involvement can vary from informative to consultative ending in participation(103). According to Arnstein's "ladder of citizen participation" (125), users may be involved at different levels, ranging from manipulation and therapy through information and consulting to partnership, delegated power and citizen control. User-centered design is placed in the latter. Many strategies may be taken to obtain a user-centered approach. Participatory design is one of them (103).

Participatory design (PD) focuses on the involvement of stakeholders, overcoming organizational barriers and roles, and thereby establishing ownership of design solution within an organization (126). Three issues dominate the discourse about PD: 1) the philosophy and politics behind the design concept, 2) the tools and techniques supplied by the approach and 3) the ability of the approach to provide a realm for understanding the socio-technical context and business strategic aims where the design solution are to be applied (127). A core principle of PD is to allow stakeholders to participate actively in design activities, giving them the power to influence design solutions by participating on equal terms (128). PD includes a conglomerate of tools and techniques e.g. observational studies, questionnaires, diagrams, pictures, photos, interviews, workshops, role-playing and simulated environments, mock-ups and prototyping (126), as well as full-scale clinical simulation (129).

Human computer interactions, which is mostly relevant for the design and evaluation of information systems (130). Computers and software operate invisibly, often leaving the user with very little information about the state of the system (131). The user interface gives the user an opportunity to interact with the computer and to receive feedback about the status of the system. Poor user interface design greatly increases the likelihood of errors (132), while good interface design makes software easier to learn, improves performance speed, increases user satis-

faction and reduces errors (133). Types of user interfaces in healthcare may be interfaces of devices or graphical user interfaces in CIS (134).

User requirement specification

"*Understanding user requirements is an integral part of information systems design and is critical to the success of interactive system*" (135) p133. The benefits may include increased productivity, enhanced quality of work, reduction in support and training costs, and improved user satisfaction. Analysis of user requirements is not a simple process, due to e.g. complex organizational situations with many stakeholders (135) and users not knowing in advance what they want from future systems (136). As described earlier in relation to the user-centred design cycle, specification of user requirements is essential as indeed is specification of context of use in order to create the full picture of how new technology must fit into the working and living patterns of the users to allow them use the new technology efficiently and effectively (137). Various methods may be used for capturing context of use along with user requirements, e.g. contextual inquiry (138), ethnography (139), and scenarios (140; 141).

Triangulation strategies are beneficial in the specification of user requirement and may increase the reliability of user requirement investigations (142). Identification of user requirements should not be considered a linear process. Maguire (135) describes a general process for user requirements with iterative identification and evaluation activities as seen in Figure 4. To ensure a successful outcome, user needs should not only be elicited by techniques, such as interviews and surveys, but should also be reflected back to users via simulation in order to prototype the user requirements.

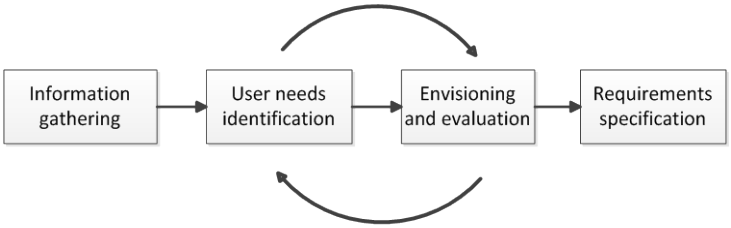
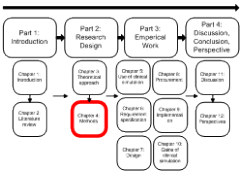


FIGURE 4 GENERAL PROCESS FOR USER REQUIREMENTS ANALYSIS BY MAGUIRE

Bødker et al (33) also emphasize the principles of user involvement and organizational roots. Information gathering may be made by analyzing stakeholders, context of use and tasks. User requirement identifications may be achieved by means of focus groups, interviews, personas, scenarios and use cases, as well as future workshops. Envisioning and evaluation may be done by card sorting, affinity diagrams, storyboards and prototyping. Requirements may be specified by use of task mapping, prioritization and criteria setting.

This section has described my theoretical approach, which is explorative. I attempt to understand rather than to explain. I have therefore embraced an interpretive approach, perceiving myself as a traveler seeing the world as a social construction, and trying to understand it through dialog with the people who live in it. This section has also provided an overview of different approaches to designing human technologies that are relevant to my research. The next section will present the methods and case studies that have been part of my research.



4 METHODS

This section outlines the methodological approach and includes a short introduction to clinical simulation and fidelity. It then presents an overview of characteristics of the five case studies and a description of each case study.

The methodological approach to my research was structured in an action-learning cycle. As shown in Figure 5, actions and reflections in the action-learning cycle are broken down into phases of planning, acting, observing and reflecting (143). In the constructive part of the cycle, planning and actions are made while observation and reflection take place in the reconstructive part of the cycle. Each phase is validated by the previous phase and looks ahead to the next. The cycle may start at any stage and does not stop after one circuit has been completed, but rather begins a new.

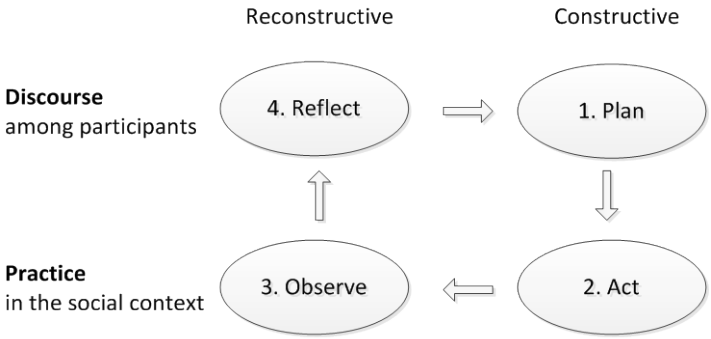


FIGURE 5 ACTION-LEARNING CYCLE

My research has been a mixed research study using both quantitative and qualitative methods with the main emphasis on qualitative methods. My intention is to understand rather than to explain (62). An initial literature review was conducted. The basis for the further experiments and case studies was clinical simulation. The empirical data was collected during the case studies using the methods described below. The different methods are highlighted in italics.

Clinical simulations involve real end-users as they simulate the use of technology in realistic environments performing realistic tasks (48). A simulation or a simulator may be defined as: a process or a device "that attempts to re-create characteristics of the real world" (144). As shown in Figure 6, clinical simulation can be used in different activities at various phases of the development life cycle of CIS from analysis of work practice and user requirements till application assessment in work practice and assessment of training programs.

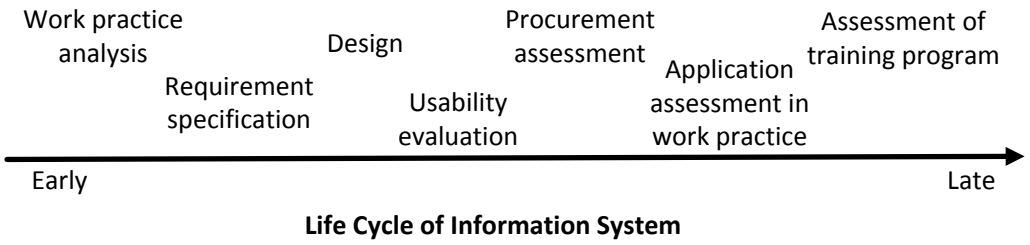


FIGURE 6 ACTIVITIES IN LIFE CYCLE OF AN INFORMATION SYSTEM USING CLINICAL SIMULATION

The realism and acceptance of the simulation depend on the degree of fidelity in the simulation set-up. The degree of fidelity may be defined as: "*The degree to which the simulation replicates reality*"(144) and is an index of how well the simulated environment resembles the characteristics of the real world. According to Beaubien and Baker (144), acceptance of fidelity in medical training comprises several dimensions. Dahl and colleagues (61) have compared fidelity in training with fidelity dimensions in the simulation-based usability assessment of mobile technology for hospitals. Their study identifies a set of fidelity dimensions and explains how the configuration of these fidelity dimensions reflects various degrees of realism. Figure 7 shows the simulation acceptance model by Dahl et al with four fidelity dimensions: environment, equipment, functionality and tasks. These fidelity dimensions affect the perceived realism and thereby acceptance of the simulation made by the involved clinicians.

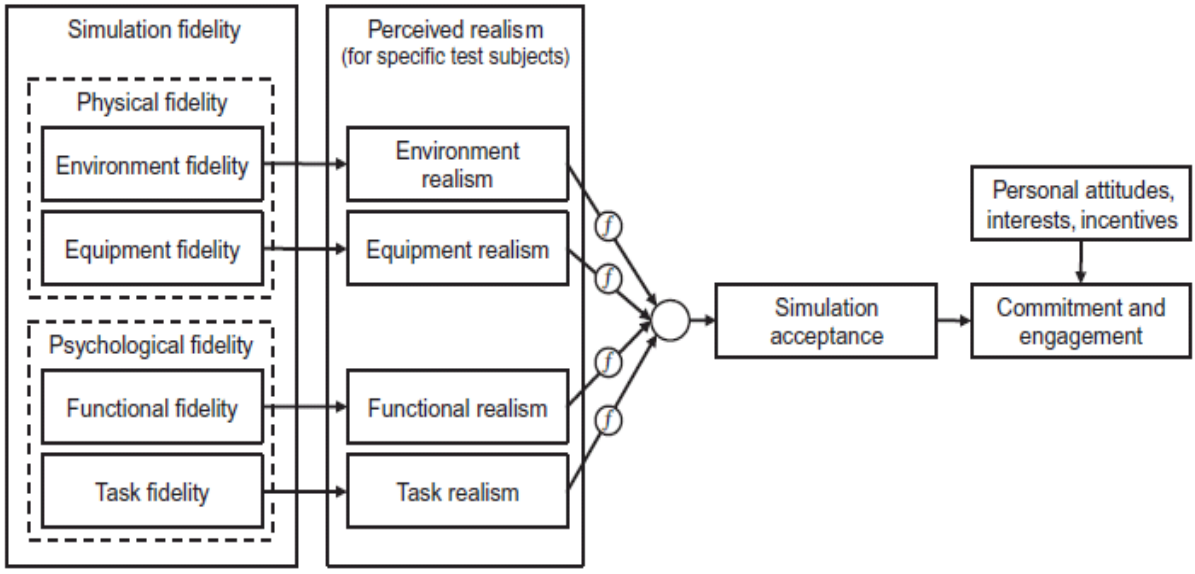


FIGURE 7 SIMULATION ACCEPTANCE MODEL BY DAHL

In my research I have used the following fidelity dimensions based primarily on Dahl et al:

- Environmental fidelity: the extent to which physical elements, such as rooms, beds and patient are realistically represented in the simulation
- Task fidelity: the degree to which the clinical task involved in the simulation for a given domain (e.g. administration of drugs and ward rounds) is replicated in the simulation
- Equipment fidelity: the extent to which elements, such as mock-ups and electronic devices, are replicated for participants in the simulation to work with

- Functional fidelity: the degree to which the technology reacts like "the real thing" (e.g. system functionalities and interactive devices).

Clinical simulations are performed in three phases; 1) introduction, 2) simulation, 3) evaluation. Prior to the simulation, the participants are introduced to the information system and to the simulation. During the simulation, a simulation facilitator is located in the simulation room. The facilitator facilitates the simulation and supports the participating clinician. An instructor located in the observation room instructs the patient and the simulation facilitator. The simulation is observed by health informatics experts and sometimes by key stakeholders, such as colleagues from hospitals, clinical managers, quality managers and vendors (145). The observers are located in the observation room. The various roles are described in Table 1.

TABLE 1 DESCRIPTION OF ROLES IN CLINICAL SIMULATION

Roles	Description
Instructor	Overall responsible for the simulation. Instructs simulation facilitator and patient(s) during simulation by use of intercom equipment and facilitates debriefing. Is located in observation room.
Simulation facilitator	Briefs clinicians prior to simulation and provides support during simulation. Receives instructions from and assists instructor during simulation, and conducts "obser-view" during simulation if necessary. Is located in simulation room.
Observer	Observes and makes notes during simulation; e.g. use of technology, usability, support of work practice, patient safety. Is located in observation room.
Patient	Acts as patient during simulation and receives instructions from instructor. Is located in simulation room.
Clinician	Simulates scenario. Thinks aloud during simulation. Participates as interviewee in interview

An overview of the simulation room and observation room is presented in Figure 8. The observation room with laptops and chairs is located in the right-hand corner. In the simulation, there are two beds and bedside tables placed together with a laptop computer. A one-way mirror separates the two rooms.

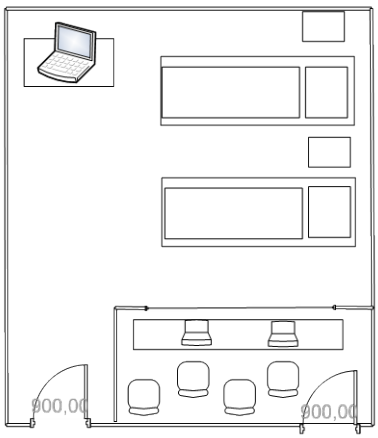


FIGURE 8 OVERVIEW OF THE PHYSICAL SIMULATION SET-UP

If possible, the clinician is asked to "*think aloud*" so that the observers can acquire a deeper understanding of the human task-behavior (146; 147). Sometimes a so-called "*obser-view"* is performed in order to gain a deeper understanding of specific issues (148). Depending on the purpose of the clinical simulation, the clinicians are sometimes also able to observe their colleagues, when not participating in the simulation themselves (149).

After the simulation, the information system is evaluated. Participants are asked to complete questionnaires and participate in a de-briefing interview. Further to interview guides, observations made by the observers during the simulations are used as background for the interviews (31). The interview and observers' notes are subsequently analyzed, e.g. using *Instant Data Analysis* (IDA) (150). IDA is a cost-saving analysis technique which allows usability evaluations to be conducted, analyzed and documented in less than a day. In a case study conducted at Aalborg University, it was discovered that IDA reduced the time required to do a video data analysis by 90%. IDA also identified 85% of the critical usability problems in the evaluated system. Results from each of the five case studies were gathered in evaluation reports.

Prior to and alongside the five case studies, *structured and unstructured field studies* on various departments and hospitals in the region were conducted using *contextual inquiry* (138) and *observations* (151). *Observations* were made during the five case studies. Additional data collection was conducted through *questionnaires* after each simulation regarding use of clinical simulation as a method for development and evaluation of CIS and *semi-structured interviews* of participating clinicians, patient safety experts and health informatics experts in connection to the case studies (63). *Data analysis* was performed using an inductive approach inspired by *Grounded theory* (152).

An overview of the empirical data and the related publications are outlined in Table 2. The empirical data was basically notes from observations, interviews and evaluations reports. The methods were chosen depending on the nature of the problems I wished to solve.

TABLE 2 OVERVIEW OF EMPIRICAL DATA

Topic	**Design**	**Empirical data**
Literature study	Search by use of MeSH Terms	Articles
Field studies	Unstructured observations	Notes
Case study Requirement analysis	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Requirement evaluation	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Design	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Procurement	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Implementation	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews

4.1 DESCRIPTION OF CASE STUDIES

Five case studies were conducted. The case studies are described in this section.

As seen in Table 3, the five cases are named according to the related activities and phases in the development life cycle. The relevant activities from Figure 6 (page 28) will be highlighted prior to the description of each of the case studies.

TABLE 3 OVERVIEW OF CASE STUDIES

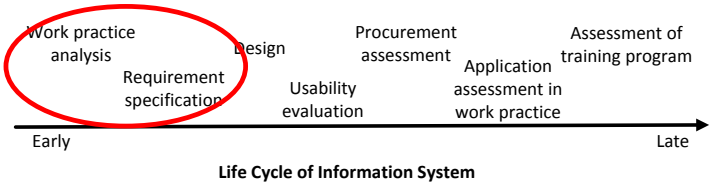
Name	**Phase in development cycle**	**Activity**
Requirement analysis	Requirement	Analysis of user requirements
Requirement evaluation	Requirement	Formative evaluation of user requirements
Design	Design	Formative evaluation of templates for nursing documentation
Procurement	Procurement	Assessment in procurement process
Implementation	Implementation	Application assessment in work practice

The five case studies encompassed different characteristics depending on how the simulation set-up was designed, i.e. fidelity applied, and when the simulation was conducted, i.e. phases in life cycle of CIS. The characteristics of the five case studies are illustrated in Table 4. The degree of fidelity applied is categorized at five levels; very low, low, medium, high and very high.

TABLE 4 CHARACTERISTICS OF THE FIVE CASE STUDIES.

Characteristics	**Requirement analysis**	**Requirement evaluation**	**Design**	**Procurement**	**Implementation**
Simulation design					
Number of clinicians	15	18	12	18	6
Number of scenarios	8	10	4	12	11
Number of simulations	18	18	12	90	11
Duration	3 days	3 days	3 days	10 days	1 day
Degree of fidelity applied					
Environment fidelity	Medium	High	Very high	High	Very high
Task fidelity	High	Very high	Very high	Very high	Very high
Equipment fidelity	Very low	Medium	Very high	Very high	Very high
Functional fidelity	Very low	Low	Very high	High	Very high

4.1.1 ANALYSIS OF REQUIREMENTS



The "*requirement analysis*" study encompassed analysis of user requirements in a large procurement of an EHR platform in Region Zealand and the Capital Region of Denmark. The new EHR platform is intended to provide basic functionalities to support clinical and administrative core processes and will be used by approximately 40,000 healthcare professionals at 12 hospitals serving half the Danish population of 5.6 million inhabitants. The study did not include an information system but was performed using a combination of low-fidelity prototypes (135; 153) and a Wizard of Oz (WoO) approach (154; 155). WoO offers interactive experience without having a real computer system and may produce adequate and sufficient input to support and extend requirement specifications (156). The method can be used to clarify user requirements without restricting users' innovativeness by asking them to work on an information system they already know. A team member acted as "The Wizard of Oz" and simulated the response from the system in form of hand-written post-it labels.

The purpose of the simulation study was to analyze user requirements concerning an EHR platform and at the same time to validate the user requirements previously specified in the project. The user requirement specifications were based on previous user requirements analysis for large EHR platforms, literature studies and workshops with healthcare professionals, quality managers, risk manager and clinical managers. The user requirements were described in use cases covering different parts of clinical and administrative work processes, and the aim of the clinical simulation study was to involve end-users and their work processes in more realistic settings in order to validate their user requirements and use cases – and, if possible, to identify new requirements.

15 physicians and nurses participated. The scenarios were not described in detail before the simulation. Patient data was not described in advance and no test data had been prepared. The scenarios were described in generic terms with no detailed information about patients and no specific context. The scenarios used in the simulation were created by clinicians nominated by hospital managers. The study scored 18 scenarios according to frequency of use and clinical relevance and the 8 scenarios with the highest scores were selected then for the validation of user requirements and use cases. The validation simulation was conducted over three days and consisted of 18 simulation runs with physicians and nurses. The participating end-users did not cover all groups of healthcare professionals. The users were selected to meet the specified scenarios covering a range of seniority and specialties.

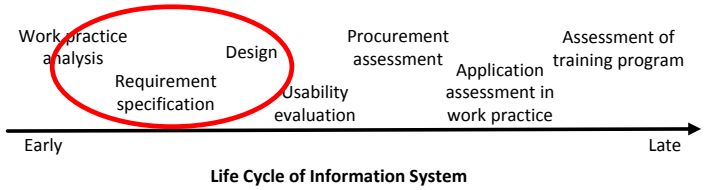
The key scenarios for the nurses were 1) dispensation and administration of drugs, 2) initial nursing assessment, 3) documentation of care, planning and status, and 4) nursing handover and distribution of tasks and responsibility. The key scenarios for the physicians were 1) ward round, 2) medical assistance, 3) admission and 4) discharge of patients. The clinicians were introduced to the aim and procedure for the simulation and asked to think of a specific patient case from one of the scenarios and then to present the scenario and the patient. The case had to be a patient they had recently treated or nursed to ensure that the details were fresh in their minds.

During the simulation, the clinician was facilitated by one of the team members who conducted an obser-view(148) at the same time. Another team member acting as WoO simulating the feedback from the information system in the shape of post-it labels (see Figure 9, left). These labels were placed on the cardboard box. A third team member acted as the patient. Figure 9 (right) shows the simulation set-up from a scenario where two nurses hand over tasks and responsibilities. The facilitator is on the left in the picture.

Figure 9 Left: cardboard boxes with post-it labels. Right: the simulation set-up

From an adjoining observation room, the clinical instructor communicated with the facilitator, the team member acting as WoO and the patient during the simulations, and facilitated the clinical details of the scenario. Two observers in the observation room recorded the clinicians' need for information and documentation as well as the work processes. The clinicians not active in the simulation observed from the observation room, reflecting on their own needs and requirements in similar clinical situations. In the debriefing interview, all the clinicians were asked about further needs and requirements, and the observations made during the simulation were discussed. The clinicians were asked how well they thought the simulation reflected real work situations. At the end of the day, the notes from the simulations and de-briefing interviews were analyzed using Instant Data Analysis (150). The results were then compared with the use cases and user requirements previously identified in the EHR platform project.

4.1.2 REQUIREMENT EVALUATION



The requirement evaluation case study aimed to demonstrate the potential benefits of a Planning and Coordination Module (PCM). The PCM-project had analyzed and specified the requirements for such a system and had built and tested a PCM prototype. End-users, clinical managers, quality managers, data architects and health informaticians performed the analysis and the specification. The purpose of PCM was to support coordination across sectors regarding the status and planning for patients with Chronicle Obstructive Pulmonary Decease (COPD) and type 2 diabetes (DM2), according to the clinical practice guidelines (CPG), and handling derived activities and services. The objective of the simulation study was to assess the potential benefits of

compliance of guidelines, quality of care, work practice, communication of a PCM for healthcare professionals involved in planning and coordination of treatment programs for patients with COPD and DM2. The study primarily focused on the efficiency of the PCM, and secondarily on satisfaction. Efficacy and effectiveness were not assessed.

The evaluation was conducted as a full-scale simulation study. The evaluation encompassed a series of 18 simulation "runs"s involving six general practitioners (GPs), six community nurses, six hospital physicians and two "patients". The simulation "runs" were bundled into six simulations. Healthcare professionals from each of the three end-user groups participated in each simulation. Ten scenarios were composed; five with a COPD patient with COPD and five with a DM2 patient. The scenarios covered 1) planning of therapy and further diagnosis for a patient recently diagnosed by the GP, 2) visitation by the community nurse, 3) rehabilitation by the community nurse, 4) treatment of a patient at an outpatient clinic due to exacerbation of the chronic condition, and 5) assignment of responsibility from the hospital physicians to the GP. The scenarios reflected different points of impact focusing on core functionalities and assignments from one healthcare professional to another. Interface issues, such as colors, buttons and minor functionalities, were not part of the evaluation as the prototype only resembled a PCM. There were no real integrations to other systems. The scenarios were designed to assess nine hypotheses related to the potential benefits of a PCM.

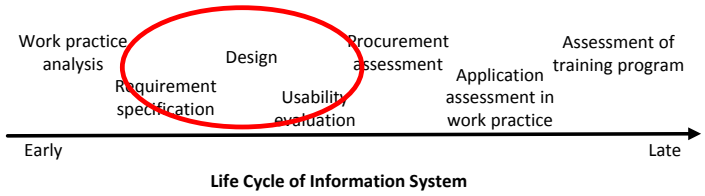
Before the simulation, the clinicians were introduced to the concept and the functionalities of the PCM. They were able to work hands-on with the information system for 30 minutes to get acquainted with it. During the simulation, the same general tasks were performed as the clinicians had trained prior to the simulations. In cooperation with the "patient" and on the basis of the patient's laboratory results and plans, the healthcare professionals were asked to revise and modify plans for the patient. The prototype had simulated integrations to other information systems in order to replicate intended integrations to legacy information systems. A simulation facilitator was seated next to the simulating healthcare professional during the simulation to assist in the event of issues related to the use of the system.

Figure 10 shows the simulation set-up. In addition to asking the clinician to think aloud, the simulation facilitator asked more exhaustive questions. By asking questions about the system, the "patient" encouraged the healthcare professional to describe the system and the functionalities in a close to real setting. Health informatics experts experienced in clinical simulations enacted the patient role. In the observation room, an instructor and several observers followed the simulation through a one-way mirror. The instructor was in radio contact with both the "patient" and the simulation facilitator during the simulation. The instructor was therefore able to direct the simulation to ensure that the objectives were covered. Observations experienced during the simulation were used in the subsequent debriefing interview. During each simulation, healthcare professionals from all three sectors were present, but only one was active in the simulation. The others observed from the observation room.

FIGURE 10 SIMULATION SET-UP

Data for the evaluation was acquired by questionnaire and debriefing interviews with healthcare professionals and observers. The questionnaire had nine questions concerning the hypothesis, two about quality, four about overview, two about the division of responsibilities, four about work practice and efficiency, and three questions about the simulation and realism of the scenarios. The interview guide started with open-ended questions concerning positive and negative features of the system, followed by specific questions to clarify and elaborate on issues from the questionnaires and other issues that came to mind. At the end of each day, the data from the interviews was analyzed using Instant Data Analysis (IDA). As supplement to IDA, the observations from the simulations, interview notes and IDA notes were analyzed using Nvivo (157).

4.1.3 DESIGN



The design case study concerned the design of electronic documentation templates and overview reports for nurses' initial patient assessment using clinical simulation. The objective of the simulation study was to evaluate 1) the content of the templates, 2) user satisfaction with the templates, 3) usefulness of the templates, and 4) the need for training in connection with implementation. Several specific parts of the templates and work practice were also addressed. The simulation was also used as an observation site and boundary object for discussions between different communities of practice.

The first version of the electronic documentation templates had previously been rejected by end-users and hospital management due to disagreement about the documentation procedure between the various stakeholders in the organization. Problems regarding acceptable time consumption as well as the need for rigorous design of the templates (i.e. clinical content, number of highly structured fields and overview of patient data, and differences in work practices) were key issues in the rejection. It was decided to address the organizational disagreements by redesigning the templates using a PD approach and clinical simulation, in which the various stakeholders in the design process were to be consistently involved. The overriding aim of the redesign process was to create a new set of structured templates that concurrently supported the daily clinical work practices of the nurses and adjusted the documentation in accordance to the

regional guidelines and accreditation requirements. In order to achieve this it was necessary first to establish consensus on the template design among the clinical nurses, quality units and nursing managers at all 12 hospitals in the region. Furthermore, the templates had to be applicable for use by nurses at all types of bed wards. Essentially, we sought to ensure that "one size fits all. Specifically, the re-design had to respond to all the major criticisms disclosed in the first pilot implementation. It was argued that the templates should:

- Handle highly structured data entry in an efficient way
- Support daily nursing work practices.

Multiple stakeholders with many different views and positions were involved. The activities in the re-design process are illustrated in Figure 11. Nurses with specialized knowledge of documentation and accreditation requirements from all the regional hospitals participated in the workshops. At the first workshop, a prototype designed on the basis of the evaluation of the first version was presented to the participants. The nursing processes were then discussed and compared to the features of the prototype.

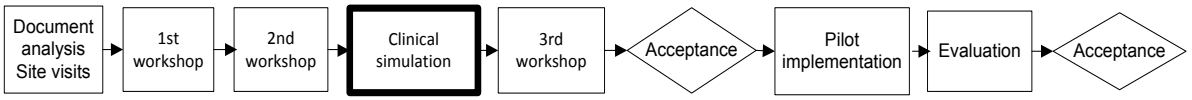
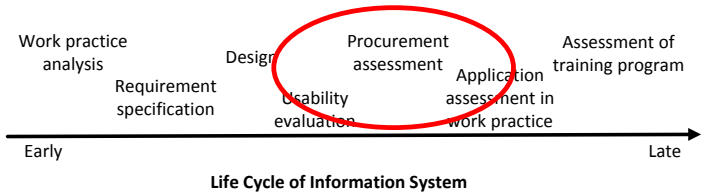


FIGURE 11 THE RE-DESIGN PROCESS INCLUDING CLINICAL SIMULATION

A new version of the templates based on the comments was presented and discussed at a second workshop. The prototype was subsequently further adjusted based on the comments from the workshop. After the second workshop, clinical simulation was conducted. During the clinical simulations, the stakeholders were able to observe the new technology in use. The interviews and discussions that followed gave us an opportunity to obtain and understand work practices and user requirements, and helped to reveal divergences of opinions between the stakeholders. The clinical simulation offered a shared mental model and supported discussion and an understanding of other stakeholders' views.

The clinical simulations were performed in realistic environments and with realistic scenarios from actual patient cases. All scenarios were based on patients assessed at the hospital within the first 24 hours. In some scenarios, a nurse made a full initial nursing assessment, whereas in others half of the assessment was previously documented and the nurse was asked to complete the documentation. This meant that the scenarios covered hand-over situations. Eight nurses simulated the scenarios. An actor played the role of the patient in order to make the simulation realistic. Delegates from other communities of practice observed the simulation from an adjoining observation room. Debriefing interviews were held with the nurses after the simulations. The observers also participated in the interview and were able to ask questions during the interview. After each interview, the observers discussed their observations and the outcome of the interview. The observers had also attended the workshops, and each delegate contributed in line with his or her background and place in the organization. Each had a well-defined role and responsibilities (81). The purpose of the clinical simulation and subsequent discussion was not to achieve unanimous consensus but to provide input for others to make the final decision. Before the final decision was made, a third workshop was held, in which the results of the clinical simulation and the subsequent negotiation were discussed. Further details are presented in publications B: *Achieving IT-supported standardized nursing documentation through participatory design* and I: *Boundary objects in clinical simulation and design of eHealth*.

4.1.4 PROCUREMENT



This procurement case study was also part of the large procurement of the EHR platform (158) and thoroughly described in "H: *Evaluation of a Clinical Simulation-based Assessment Method for EHR platforms*" and section 4.1.4. In contrast to the case study regarding user requirement analysis, this study related to the actual procurement, where, following negotiations, three vendors were selected for the final selection process. The purpose of the case study was to assess user satisfaction, usefulness and patient safety in three different solutions. The new EHR platform contains broad functionality to support clinical and administrative core processes. The platform is to be used by approximately 40,000 healthcare professionals. The two purchaser regions stipulated a strategic requirement for user involvement in the procurement process. The purchasing regions requested that the assessment of the systems on offer should cover usability and human factor issues as well as system impact on a variety of working contexts. The procurement was the largest of its kind in Denmark and the new EHR platform is to be implemented at approximately 14 hospitals serving half of the Danish population.

The applied assessment methods had to cover the demands of various end-users, specialties, and cultures, and also meet the transparency demands of procurement in a public tender in accordance with EU regulations. The procurement focused on increased effectivity in quality of care. This was expressed by demands for qualitative and quantitative improvements in three areas: 1) continuity of care and patient safety, 2) streamlining of clinical processes and workflow, and 3) patient and employee satisfaction. Furthermore, cross-functional work processes and overlap of responsibility were topics of great concern. Three vendors were chosen for more thorough assessment, including a detailed assessment of the EHR platforms they offered.

A major challenge when applying clinical simulation as an assessment method in a procurement process is to convert the qualitative aspects of the process into quantitative output. The qualitative human factor aspects in the assessment were to be revealed. To do this, a new method was developed for assessment in the procurement process. The assessment method was developed on the basis of literature studies, ISO standards concerning usability requirements and seven years of experience of using clinical simulations for development and design of CIS (30; 145; 149; 159). The method was designed to uncover qualitative human factor aspects in the assessment and to include typical use scenarios and real end-users. Finally, the method had to take into account the perspectives of various stakeholders, including risk managers, quality managers and clinical managers. The basis of our assessment metrics was based on ISO standard 9241, Part 11 concerning usability in ergonomic requirements (100).

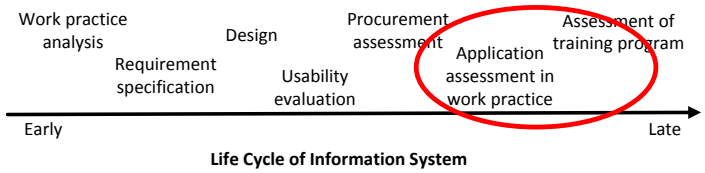
The assessment covered 12 clinical scenarios and 18 health professionals from various specialties and professions. Three EHR platforms were assessed during a period of 10 working days. The clinicians had a full day of training in each of the three platforms followed by two days of clinical simulation. Having completed one simulation scenario, the clinicians assessed how the tested platform supported the task. The assessment was scheduled for three consecutive periods of three-day, during which the clinicians would scrutinize all three EHR platforms. The clinicians

who were not part of a specific simulation followed the simulation from the observation room (see Figure 12).

FIGURE 12 SIMULATION SEEN FROM OBSERVATION ROOM

The evaluation of the assessment method was to respond to the following questions: 1) how eligible is the method?, 2) what are the advantages/disadvantages compared with other assessment methods?, and 3) does the evaluation of the method reveal issues that must be improved? The evaluation of the method was qualitative and included observations and semi-structured interviews of key actors and participating clinicians. Observations were conducted during all 10 assessment days. On the final day, all the clinicians were interviewed. Subsequently 15 interviews were conducted with project and legal managers, health informaticians, vendors, patient safety experts, and observers during the clinical simulations. The qualitative approach allowed us to conduct the evaluation without interfering with the assessment process, and concurrently obtain thorough insight into user experiences and the perceived benefits and challenges of the method. All interviews were transcribed and analyzed using a qualitative approach of content data analysis.

4.1.5 IMPLEMENTATION



The implementation case study primarily encompassed work practice and the usefulness of a facility for doctors to sign for laboratory results with the objective of assessing the work practice, usefulness, user satisfaction and patient safety of the new application. For a long time, the Capital Region of Denmark has sought to obtain an IT- supported work flow for physicians receiving and signing laboratory test results in order to improve patient safety. In the existing workflow this was done on paper; i.e. prints were made from digital systems in order to document that test results had been reviewed by a doctor. The laboratory tests were handled by various information systems. Some test results were on paper and others were electronic. The

background for the local work flows was based on interpretations of a national guideline for handling laboratory test results. The national guideline was developed as part of a quality assurance initiative to increase patient safety. As a rule, the physicians sign to confirm that they have seen a laboratory test result. The physician also signs to confirm that he or she has handled the test results in the patient's record. The essential challenges about the paper based workflow were 1) lack of overview about whether a result has arrived, 2) uncertainty about whether a test result has been seen by a physician, 3) lack of documentation about which physician has seen a test result. The objective of purchasing the IT-system was to increase quality in work practice and minimize the risk to patient safety by implementing a new standard information system, "OPUS inbox", which collects laboratory test results and supports electronically documentation of acknowledging the results.

The study was expected to be moderate and manageable because the information system was a standard off-the-shelf product and the intended work flow was supposed to be narrow and well-defined. The information system was to be implemented at two pilot departments. Both departments included patient wards and outpatient clinics. Prior to implementation, the existing work practice was analyzed and future generic work flows defined. The functionality of the information system and collaborative future work practice were evaluated by means of clinical simulation.

The aim of the implementation case study was to assess the potentials of clinical simulation as a proactive method by which to identify and evaluate potential patient safety hazards prior to implementation. The aim of the simulation evaluation was to examine how the "OPUS inbox" system supported clinical practice and to identify potential patient safety hazards prior to its implementation.

Initial field studies were carried out at the two pilot departments covering both patient wards and outpatient clinics in order to gain insight into existing work practice concerning receipt, handover and acknowledgement of laboratory test results. Two workshops were then held with physicians, nurses and medical secretaries from the pilot departments, health informaticians and experts from the regional quality unit. At the first workshop, future work practice and the information system were analyzed and required changes were identified. At the second workshop, future work practice was determined, focusing on improved efficiency, quality, continuity and communication. Existing routines were contested and organizational changes were initiated ahead of implementation in order to create acceptance and a readiness to change among future end-users.

In order to evaluate patient safety, usefulness and usability clinical simulation was conducted after the workshops. The purpose of the clinical simulation was to evaluate patient safety issues and future work practice using the new information system before its implementation. Six healthcare professionals from the two pilot departments (two physicians, three nurses and one medical secretary) were selected to participate in the simulations. The observers were clinical managers from the pilot sites, implementation experts and health informatics experts. Figure 13 shows the simulation room seen from the observation room through a one way mirror. To the left are the observers in the observation room. To the right is an outpatient clinic set-up where a physician is preparing for a meeting with a patient.

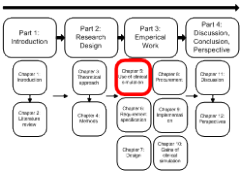
FIGURE 13 LEFT: OBSERVATION ROOM WITH OBSERVERS. RIGHT: SIMULATION ROOM SEEN FROM OBSERVATION ROOM

A total of 11 scenarios were performed during the evaluation; six scenarios from patient wards and five scenarios from outpatient clinics. All scenarios were related to signing and handling laboratory test results. Some of these were frequently performed work flows; e.g. ward rounds and visits to the outpatient clinic, while others were critical work flows; e.g. urgent test results and sorting test results and handover of responsibility. The simulation set-up was very realistic. The computers used were identical with those used at the hospitals and the system was fully developed and operational. The scenarios were composed in participation with clinicians from the pilot sites and based on realistic patient cases. The simulation room was designed as either a ward bedroom or clinical office. The role of patient was enacted by a healthcare professional.

Clinical simulation as a method was evaluated by means of interviews with the project manager, a manager from one of the pilot hospitals and an expert from the patient safety unit. The pilot implementation was evaluated at a workshop with clinicians, clinical managers, and representation from the patient safety unit and the quality unit, and used to decide whether the information system should be implemented at the remaining hospitals.

After a 4-week pilot implementation at the first pilot site, the implementation was evaluated. In the end the system was stopped and the project was terminated.

This chapter has presented my methodological approach and given an overview of the characteristics of the five case studies as well as a description of each. The findings of the five case studies will be presented in the following sections, starting with key issues and concerns in the engineering of clinical simulation, which will be presented in the following section.



5 RESEARCH FINDINGS – USE OF CLINICAL SIMULATION

In this section, I discuss the research question "*How can clinical simulation be used in the development and evaluation of clinical information systems?".* The aim of this section is to describe a methodological approach for planning, preparing and conducting clinical simulation highlighting the most important key issues and concerns in the shape of 10 steps towards a successful simulation. These 10 steps are highlighted throughout the section. Reference is made to the publication "J: *Clinical Simulation –A Method for Development of Clinical Information Systems*". The publication is inspired by more than 25 clinical simulations performed in the ITX-lab since 2007, and is based on the five case studies included in my research. The case study "Requirement evaluation" (described in section 4.1.2, page 33) is used as a recurrent example in the publication.

Clinical simulation may be part of various activities in the human-centred design cycle; *plan the human-centred process*, *specify the context of use*, *specify user requirements* and *evaluate against requirement*. These activities are highlighted above.

Purpose:

The first step is to define the purpose of the clinical simulation. The purpose of clinical simulation may vary throughout the different stages of the development life cycle (53). In the early stages, the purposes may be to analyze work practices and user requirements (149; 160). In the design phase the purpose is often to create a shared understanding of new technology and work practice as well as to evaluate the design and user interface (145; 161). Before an information system is implemented, the purpose may be to learn more about various aspects of implementation, such as the need for training and the influence of the new technology on existing or new work practices, including patient safety (31; 162). As indicated in Figure 14, engineering of clinical simulation includes iteration and agile phases. The purpose influences the planning and preparation of the study and establishes the scope of its actual performance. It is therefore important that the purpose is focused, defined in close cooperation with key stakeholders, and accepted by the owners of the project (31).

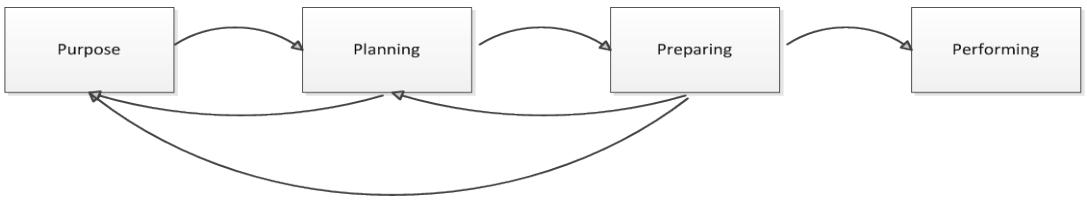


FIGURE 14 ITERATIVE PHASES IN ENGINEERING CLINICAL SIMULATION

During the planning and preparation phases, new knowledge may be acquired, which may lead to redefinition of the purpose.

Step 1:
The purpose of the clinical simulation must be focused and rooted in the organization

Planning

The planning phase starts by defining the scope, which includes scenarios, number of simulation "runs" and the number and profiles of participating clinicians. Each scenario reflects typical tasks in a small fraction of clinical work practice. Together the scenarios should more or less cover the parts of work practice affected by the new technology; reflecting the purpose (149).

> **Step 2:**
> Choice of scenarios is crucial and must reflect the purpose of the clinical simulation

The profiles of the participating clinicians and observers must reflect both the purpose and the scenarios. If the technology covers broad functionality used in many different specialties and by many different groups of healthcare professionals, the number of scenarios and simulations must be higher than if the technology was used by e.g. physicians in a very specialized field for a very specific purpose. Choice of profiles may also have to reflect experience in healthcare as well as in the use of technology; again depending on the purpose of the simulation (31).

> **Step 3:**
> Choice and profile of clinicians must reflect the purpose of the clinical simulation

Preparing:

Having dealt with the overall frame, the simulations have to be prepared. Preparation includes writing scenarios and designing the clinical and technical set-up. Complex scenarios and patient cases are resource demanding tasks and the need for complexity must therefore be carefully considered, and must reflect the purpose and frame of the simulation (31).

> **Step 4:**
> Complexity in scenarios and patient records must be carefully considered

Planning and preparing clinical simulation may be time-consuming, but careful preparation of the clinical and technical set-up entails effective time spend by the clinicians (162).

> **Step 5:**
> Planning and preparing clinical simulation is resource demanding in order to make it effective for clinicians

As mentioned earlier, the simulation process attempts to re-create characteristics of the real world (144). The need for fidelity in the recreation of the real world depends on the purpose of the simulation. Dahl et al presents four characteristics of fidelity in clinical simulation (61). These characteristics are described in section 6 *Research findings* - requirement specification. The need for fidelity varies depending on the purpose of the simulation and the stage reached in the life cycle of the information system. The fidelity dimensions include equipment fidelity, environment fidelity, task fidelity and functional fidelity (61). Equipment and functional fidelity correspond to the maturity of the technology, while environmental and task fidelity correspond to the clinical context. If the purpose is to assess technology, equipment fidelity and functionality fidelity needs to be high. Where simulations focus on work practice, the need for equipment fidelity and functionality fidelity will be lower (160). If the purpose is to assess patient safety issues ahead of implementation at a hospital, all fidelity characteristics need to be high (162). In

clinical simulation, characteristics concerning clinical context should not be low. A high degree of task fidelity is pivotal to clinical simulation and environmental characteristic such as the patients, colleagues and physical environments are important in order to stimulate the cognitive acceptance of the simulation (31).

Step 6:
The degree of fidelity must reflect the purpose of the clinical simulation and the maturity of the technology

Rehearsals are well worth the effort. Pilot testing the simulation before bringing in the participants for real simulation runs is valuable because unrealistic scenarios, interruptions and delays influence how participants accept the simulation (31). Rehearsals may be conducted on scenarios, the clinical set-up, technical set-up and data collection.

Step 7:
Rehearsals and pilot studies are important and well worth the effort

Performing:

In order to create a high degree of clinical fidelity, the participating clinicians must be familiar with real work practice. Quality nurses, clinical managers etc. are appropriate to use as observers but cannot replace end-users in the simulation (30; 161). During the simulation it is beneficial to observe the simulation through a one-way mirror or by using video recordings. Thereby it is possible to let specialists and key stakeholders focus on other issues, such as the need for user interface training, organizational and technical challenges and patient safety issues (149).

Step 8:
Real clinicians (end-users) should be used as participants

Data collection and analysis:

Data collection may be performed by means of questionnaires and interviews (31). The validity of using questionnaires depends on the number of participants, but they may serve the purpose of encouraging the participants to reflect on specific issues (31). The composition of questions in questionnaires and interviews should reflect the purpose of the simulation. Observations and reflections made during the simulation may be used as input during the interview. The simulation may also be video recorded. These recordings may also be used during the debriefing interview or analyzed afterwards. In the case studies, data from interviews and observations were analyzed using a cost-saving analysis method *Instant data analysis* (IDA)(150).

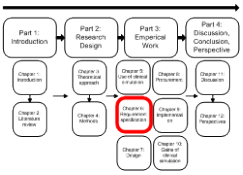
Step 9:
Cost-saving analysis methods, such as IDA, are very useful and can be applied to analyze the resultant data

Finally a report is composed on the basis of the findings of the simulation study. The report includes results and recommendations. It must be clarified in advance to whom the results are to be presented and how the results and recommendations should be implemented. Furthermore, the participants' and observers' respective mandates must be clear (161).

Step 10:
The clinicians' and observers' respective mandates must be clear. It must also be clear how the results will be used, reported and implemented

As scenarios often only cover fractions of the clinical work practice, clinical simulation cannot substitute pilot implementations. In a pilot implementation, an information system is implemented in a small and controlled environment for a shorter or longer period. Time-based elements are not well-matched with clinical simulation. Getting acquainted to new technology may take time and clinical simulation does not reflect the social-technical impact over time.

This section presented a methodological approach to engineering and conducting clinical simulation. 10 steps to a successful simulation have been highlighted. The next section will discuss how clinical simulation can be used in activities related to user requirement specification.



6 RESEARCH FINDINGS - REQUIREMENT SPECIFICATION

In this section I discuss the research question "*What are the potentials of using clinical simulation in specification of user requirements for clinical information systems*?". The discussion is based on two case studies. The first study investigated the analysis of user requirements (see section 4.1.1 Analysis of requirements) and the second case study (see section 4.1.2 Requirement evaluation) investigated formative evaluation of previously specified user requirements. Human-centred activities in the first case study are highlighted in red above, and activities in the second case study are highlighted in blue. The simulation set-up in the two case studies differed widely where equipment and functional fidelity were concerned. The two different approaches are discussed in the following. The publications related to the research question are: 1) D: *Fidelity in clinical simulation – how low can you go*? (160), and 2) C: *Benefits of a Clinical Planning and Coordination Module* (149).

Preparing clinical simulation can be quite resource exhaustive and the degree of fidelity should therefore correspond closely to the purpose of simulation (31). High fidelity prototypes may not be accessible for analyzing user requirements in the very early stages of the life cycle (135). In the first case study (see section 4.1.1), the goals were to validate previously identified user requirements and use cases and, if possible, identify new requirements and use of work (160), and, thirdly, to explore the lower limit of degree of fidelity required to perform an effective clinical simulation study.

There was no fully functioning information system in the study. We used a simple mock-up in the form of cardboard boxes with post-it labels for input and output from the 'system' (153). We used a WoO approach to simulate the functionality of the information system. WoO offers interactive experience without having a real computer system and may produce adequate and sufficient input to support and expand requirement specifications (154; 155). The scenarios were not described in detail before the simulation. No patient data were known in advance and no test data had been prepared. The scenarios were described in generic terms without detailed information about the patient or the specific context. Just before the simulation began, the clinicians were asked to think of a specific patient case and describe the scenario and patient. The actor playing the role of the patient acted according to the clinician's description of the patient.

The simulation provided an opportunity to focus on context-sensitive needs. It examined clinical work practice and user requirements for information and documentation across various use cases and work processes, in a range of frequently used scenarios(160). Due to the rather high fidelity tasks and environment, the simulation stimulated the clinician's experience of working practice despite low functional and equipment fidelity. The realism of daily work practice and the interactive experience with the prototype supported the creativity of the clinicians. The clinicians found the interaction with the patient vital in order to make the scenario come alive. However, the patient was required to act in accordance with the scenario described by the clinician ahead of the simulation. In a few scenarios, the instructor attempted to change the behavior of the patient by issuing new directions through the intercom, which confused the simulating clinician.

As result of the simulation, previously specified user requirements were validated and new user requirements were identified. Some requirements were not clarified sufficiently during the simulation study but were clarified later in discussions with the vendors during the dialog phase. The realism of the simulation and the simulation with other healthcare professionals and patients supported the identification of new cross-disciplinary requirements.

The simulation study also resulted in useful knowledge concerning daily work practice. This information was not new but had not arisen in the previous workshops. Clinicians have vast amounts of implicit knowledge of the activities and processes which may go unmentioned in typical experimental settings. However, if health information systems are to be designed on an informed basis, it is imperative that this knowledge is made explicit. Different methods should be used to elicit this implicit knowledge. Lucy Suchman describes how work processes may be invisible to others and how working processes are perceived differently by different people. The better a work practice is performed, the less visible it is, which makes it difficult to describe (32).

TABLE 5 DEGREE OF FIDELITY USED IN REQUIREMENT ANALYSIS SIMULATION

	Low	High
Environmental fidelity		Realistic physical environments and a 'patient' supported the perceived realism
Task fidelity	"Obser-view" during simulation No test data in advance	No limitation of designed cases allowed participants to align scenarios with personal work practice and own patient cases
Equipment fidelity	No limitation of known technology allowed for unrestricted ideas about the ideal EHR platform	
Functional fidelity	No limitation of known functionality supported imagining the functionality of the ideal EHR platform	

Table 5 shows the fidelity dimensions and the degree of fidelity in each dimension in the requirement analysis study. Scenarios are part of the task fidelity and, in this case, the task fidelity may be split into two parts: the scenarios were very realistic as they were taken from real life, but the actual simulation of the scenario was not as realistic. During the simulation, the clinicians were asked about the need for information and documentation.

When using scenarios described by the clinicians, it is important to follow the scenario. If the "patient" tried to change the scenario, the clinicians became confused and fidelity plummeted. This issue was a severe limitation in the simulations. We were stuck with the scenario. On the other hand, it was realistic. The debriefing interview compensated for this limitation. During the debriefing, it was possible to ask more specific questions about other types of scenarios and situations.

The realistic scenarios and the dialog with the patient were important elements in maintaining task fidelity. Senior clinicians often generate higher task fidelity. However, if we allow clinicians to describe a real life scenario, less experienced clinicians are able to maintain high task fidelity. This limits the number of clinicians that can take part in the same simulation as, if they are to do simulations together, they must have experienced the same situation. Part of the task fidelity was low because the test data was not specified in advance. The environment fidelity was high due to the realistic clinical environments in the simulation lab. This helped the clinicians to think about physical aspects of their work in relation to a new information system.

The degree of functional fidelity in the prototype was low as we were using post-it labels as input and out from the IT-system. Low fidelity prototypes present no richness of interactivity and are of no use in evaluating interactive features. The use of cardboard boxes represented low functional fidelity but helped to simulate interaction with the computer. In the same way, the post-it notes helped to preserve a certain degree of functional fidelity. These types of clinical simulation may be regarded as more suitable for analyzing less detailed user requirements. When examining very large health information systems, low functional fidelity is more suitable for analyzing user requirements broadly than at a very detailed level. The equipment fidelity concerning devices in the system was low. However, this helped the clinicians as they were not hindered by familiarity with the devices they usually use or by devices chosen for the project.

The observing clinicians are can dissociate themselves from the simulation and reflect on how things would be in other situations. These reflections may be discussed in the debriefing along with other observations and questions that may arise during the simulation. The results of the clinical simulation were validation of previously known user requirements, and a means by which to connect these requirements with realistic work practice and thereby identify context sensitivity requirements.

In the second case study (see section 4.1.2) concerning requirement specifications, the purpose was to evaluate already identified requirements (149). The purpose of the study was to assess benefits and challenges of a planning and coordination module. To realize the intended benefits of a PCM, the usability of the system is pivotal (163), and should be reflected back to users (135). Compared to the requirement analysis simulation study, this study was conducted with a higher degree of fidelity. The CIS was a relatively mature prototype of a planning and coordination module built on the basis on an operational information system with a user interface designed to realize the user requirement already specified. The main focus of the evaluation focused more on the concept of the module and potential inherent in such a module and less on the user interface, because the user interface was designed only as an example of how such a system could look. The focus was more on functionalities and usefulness than on ease of use. Integrations with other systems were faked. The system was basically designed to establish and maintain a cross-organizational overview and virtualized management of all health services in individual patient cases among all relevant healthcare actors. The system was meant to be used across sectors by general practitioners, community nurses and hospital doctors.

Most of the clinicians found it difficult to understand the concept of the information system in spite of having been introduced to it prior to the simulation. The concept was innovative and forced the clinicians to view planning and coordination in a new way. The simulation itself and the observation of other clinicians using the information system helped the clinicians to understand the concept. Overall the system was assessed as very useful. The results of the evaluation showed that the PCM would increase clinical value, e.g. by presenting the recommended activities in the continuity program and displaying an overview of the plans and activities during the course of a disease. The participating clinicians concluded that quality of care would improve. The clinicians found that the PCM would be beneficial for the patients, although no real patients were included in the evaluation. Had real patients participated, the outcome of the simulations would have been better..

New future users were identified and new potential ways of using the system were revealed. The system was found to be a powerful learning tool for the new users in spe. Several new issues of concerns were brought up concerning sharing responsibilities and terminology.

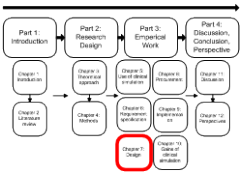
As in the case study concerning analysis of requirements, the degree of task and environmental fidelity was high. In the requirement specification study, the degree of functional and equipment fidelity was also high. The PCM was a fully functional prototype. The user interface was not complete but the users were nonetheless able to use all the functionalities. All integrations were faked and the users experienced using the PCM as if it was integrated to adjoining IT-systems. Table 6 shows the degree of fidelity used in the requirement evaluation study.

TABLE 6 DEGREES OF FIDELITY USED IN REQUIREMENT EVALUATION STUDY

	Low fidelity	**High fidelity**
Environmental fidelity		Realistic environments supported the perceived realism
Task fidelity		Realistic patient cases allowed participants to align scenarios with personal work practice and own patient cases Realistic test data implemented in prototype
Equipment fidelity		Fully functional prototype
Functional fidelity	Simulated integrations	Fully functional prototype

As stated by Maguire (135), users should participate in user need identification, and envisioning and evaluation. These activities and specification of the context of use are also part of the human-centred design model (52). The requirement analysis study was an analysis of work context and user requirements whereas the requirement evaluation study was a formative evaluation of previously specified user requirements. The two case studies revealed that clinical simulation made it possible to involve clinicians and the clinical context actively without endangering patient safety. Both studies might have been improved by also involving patients. Clinical simulation cannot stand alone but should be regarded as one part of a triangulation strategy (142) for specifying user context and user requirements.

In this section the use of clinical simulation in activities pertaining to requirement specification has been discussed. Findings from a case study concerning analysis of user requirements have been presented here as well as findings from a case study concerning formative evaluation of user requirements. Differences in the degree of fidelity in the two case studies have been discussed. The degree of fidelity should reflect the purpose of the simulations as fidelity has a strong impact on the results. The next section discusses how clinical simulation can be used in connection with design activities in the development of clinical information systems.



7 RESEARCH FINDINGS – DESIGN

In this section I discuss the research question "*What are the potentials of using clinical simulation in design of clinical information systems?".* Publication I: "*Boundary objects in clinical simulation and the design of eHealth"* is related to this research question*.* The publication examines how clinical simulation can be used as part of participatory design when designing CIS and discusses how clinical simulation can be used to communicate and transfer knowledge between different groups of people in order to get a shared understanding and common ground for discussions and negotiations. Clinical simulation was used to understand the context of use, specify user and organizational requirements, and evaluate design (highlighted in red in the upper right-hand corner of this page). The publication is related to the Design case study, which is described in detail in section 4.1.3.

The design case study (145; 161) dealt with re-design of documentation templates and overview reports for nurses regarding nurses' initial patient assessment. The design process (presented in Figure 11 at page 36) included document analysis, site visits and workshops, and clinical simulation was used to involve end-users actively (145). Clinical simulation was used as a boundary object serving as a media and common ground through which to communicate and negotiate in order to gain a shared understanding and reach agreement on the future design of the templates (164).

To evaluate this approach I observed and took notes from the workshop and simulation session and subsequently interviewed representative qualitative nurses, who had taken part in the clinical simulation and the design process. I also investigated reviewed the literature on boundary objects and participatory design.

The results concerning the design of the templates were (161):

- Requirements for structured data should be kept to a minimum to ease nurses' documentation processes. Many structured fields were removed and a few were added.
- Better overview of patients' record. The original overview was optimized and an additional version of the overview was designed.
- Template content requirements were aligned for the most part. The parties agreed to evaluate some minor elements during the pilot implementation. The present content focused on the most generic areas and elements of the initial nursing assessment, e.g. details concerning hearing aid were reduced.

The results of using boundary objects and the specific design method were:

- All communities of practice were involved and showed great interest in participating.
- Ownership was obtained by including all communities of practice in the process, leading to broad acceptance of the system in the organization.
- The gap between the quality nurses' theoretical approach and the ward nurses' practical approach was effectively bridged.

- Using clinical simulation as a boundary object helped to visualize the use of the templates and obtain a shared mental model.
- The de-briefing interviews and discussions, and workshops helped to align expectations and provided input for final decisions regarding template design and content.

Clinical simulations may be used as boundary objects. Clinical simulations as boundary objects are constructed at the intersection of the communities of practice of design and use of CIS. They reveal the divergences between the different communities. Relations are reshaped, alliances shifted and the balance of power realigned during the clinical simulation (164). Clinical simulation makes it possible to actively participate in design activities. Choosing a PD approach empowered the participants to influence the design solutions on equal terms, which ensured that they took ownership of the subsequent implementation of the information system.

The simulation gave important input regarding resolution of some of the practical challenges facing the daily work with documentation templates. The simulation became a boundary object because it was used at the interface of different communities of practice. By observing end-users using the templates, the discussion between the different communities of practice served as common ground, supported a shared understanding, and changed the focus to practical usage of the templates instead of a more theoretical approach to template content, which depended on the individual stakeholder's area and practice. Bowker and Star argue that "*the more at home you are in a community of practice, the more you forget the strange and contingent nature of its categories seen from outside*" (82) p294. Clinical simulation was a pragmatic approach to boundary objects and visualized the consequences and the impact of implementing an information system. Clinical simulation transformed knowledge about a process and created new knowledge. Things were depicted differently by different communities of practice and in different contexts (82). However, as in the example of Iansiti's work on the role of prototypes (165), clinical simulation enhanced the process of transforming knowledge.

Clinical simulation is conventionally used to evaluate technology but can also be used as a learning space, in which to acquire knowledge of other parts of the organization. . Clinical simulation provided the different communities of practice with an opportunity to observe and discuss the impact of the re-designed template and offered a means by which to manage the tension between divergent viewpoints, which was of great assistance in the design case study, especially where different views on content and structure of documentation were concerned. As one of the participants later said: "*We no longer discussed based on our own ideological attitude. Instead we gained a shared mental model to discuss from*". Some communities of practice found that the highly structured nature of the templates limited flexibility in the conversation with the patient and made the documentation unnecessarily complicated. Thus clinical simulation was used as a boundary object to facilitate meetings, such as de-briefing interviews, workshops and as part of the design process (79).

Prentice argues (164) that "*surgical learning occurs at the interface of bodies and instruments, through simultaneous sculpting of the surgical site and training of the surgeons body*", a process she calls "*mutual articulation*". In the same way, clinical simulation provides an opportunity to investigate the impact of work practice before it impacts the daily work in a hospital. Another way of expressing the use of boundary objects is stated by Bowker and Star (82): "*the medium of an information is not just wires and plugs, bits and bytes, but also conventions of representation, information both formal and empirical. A system becomes a system in design and use, not the one without the other*". Clinical simulation provided an opportunity to observe the system in terms of

both design and use. The simulation offered a method or approach by which to tackle the tension between divergent viewpoints.

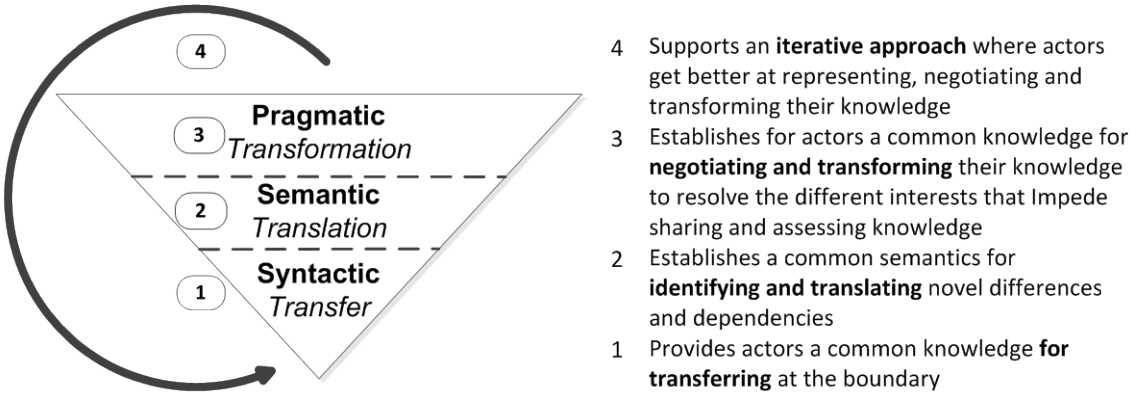
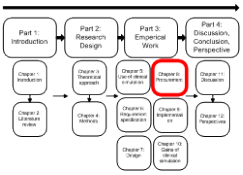
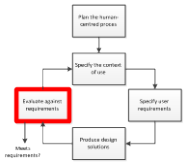


FIGURE 15 CARLILE'S INTEGRATIVE FRAMEWORK FOR MANAGING KNOWLEDGE ACROSS BOUNDARIES AND THE FOUR CHARACTERISICS OF A "PRAGMATIC" BOUNDARY CAPABILITY

Carlile describes following the three approaches to knowledge boundaries in product development: syntactic, semantic and pragmatic (77; 143) as seen in Figure 15. Clinical simulation was used as boundary object transferring and translating knowledge between different communities of practice. Clinical simulation helped in transferring knowledge from one community of practice to another and helped different parts of an organization in to gain a shared understanding of needs and requirements. Clinical simulation offered a means by which to achieve a mutual clinical agreement on the design of a new information system. Furthermore, subsequent discussion allowed all the communities of practice an opportunity to voice their point of view and to affect the final result.

This section has discussed how clinical simulation may be used in design activities regarding the development of clinical information systems. Clinical simulation can be used in a PD approach providing common ground for dialog and discussions, and supporting the acquisition of a shared understanding between different communities of practice. The next section will discuss how clinical simulation can be used in activities in a procurement process.





8 RESEARCH FINDINGS – PROCUREMENT

In this section I will discuss the research question "*What are the potentials of using clinical simulation in assessment of clinical information systems as part of a procurement process?*" The publication related to this research question is: "H: *Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms*". The publication is related to the case study regarding assessment of an EHR platform (158), which is described in detail in section 4.1.4 Procurement.

Human-centered design methods, in which the entire development process is focused on user-centered activities in order to create safe and useful applications, are well described (52; 166; 167). However, when it comes to assessing human-computer interaction and work process support in relation to procurement of electronic health record (EHR) systems, the methods are inadequately described. Even though new technology is intended to reduce errors, it is well known that CIS may introduce new types of errors; i.e. adverse events due to increased strain on cognitive processes and unintended use (3; 168; 169). Maguire and Bewan describe how scenarios, personas and prototyping may be used in analyzing user demands, and how prototyping may be used in evaluating information systems (135). Qualitative methods, including clinical simulation, may also be used to capture the cognitive aspects influencing clinical work practice in relation to any particular system (25).

Qualitative aspects, such as the interaction between technology and end-users and other human factors, are generally difficult to assess. Public procurement processes (PPPs) involve compliance with strict rules and an assessment must be quantitative in order to equally and precisely compare the information systems on offer. A PPP is typically a structured assessment of the vendors' textual descriptions of the solutions they offer and their written replies to the requirement specifications. Assessment of textual descriptions is, however, inadequate as it fails to fully assess human factor issues (38). In the procurement case study (described in section 4.1.4), clinical simulation was used to assess CIS from three different vendors. While the literature describing how clinical simulation can be used to evaluate a single information system is comprehensive, there are few publications describing how simulation can be used to systematically assess and compare several information systems and their support of clinical work processes in a PPP.

The aim of the simulation set-up was primarily to assess the three EHR platforms in the final phase of the procurement process and secondarily to actively involve clinicians in the PPP.

To gain insight into the potential for using clinical simulation for assessment in a procurement process, we developed a method based on existing knowledge and previous experience with clinical simulation. As the EHR platform was to be used in two different regions with 20 hospitals and approximately 40,000 users, the assessment methods applied had to address the requirements of various end-users, specialties and cultures. The methods also had to meet the transparency demands of procurement in a public tender process in accordance with EU regulations. Focus in the procurement was on increased efficiency in quality of care. This was expressed as demands for qualitative and quantitative improvements in three areas: 1) continuity of care and patient safety, 2) streamlining of clinical processes and workflow, and 3) patient and employee satisfaction. Cross-functional work processes and overlap of responsibility were top-

ics of great concern. In a public tender process, the results of the assessment of the various platform solutions should be quantitative in order to facilitate accurate and uniform comparisons between the offerings of competing vendors. As stated by Maguire (135), CIS should be evaluated by users. In the procurement case study, this was achieved by using clinical simulation. A major challenge when applying clinical simulation as an assessment method in the procurement process was to convert the qualitative aspects of the process into quantitative output.

To accomplish this, a new method was developed for assessment in the procurement process. The method was intended to reveal the qualitative human factor aspects of the assessment and include typical use-scenarios and real end-users. Furthermore, it had to take into account the perspectives of various stakeholders, including e.g. risk managers, quality managers and clinical managers. Our assessment metrics were based on ISO standard 9241, part 11 concerning usability in ergonomic requirements (100). The method we developed combines clinical simulation with quantitative measurement methods. The method is described more thoroughly in the publication "F: *Use of Clinical Simulation for Assessment in EHR-Procurement: Design of Method*". We used a participatory approach as the project participants and organizational stakeholders were actively involved in developing the method.

The assessment method and metrics were inspired by the usability framework in the ISO standard: "*ISO 9241 Ergonomic requirements for office work with visual display terminals (VDTs) - Part 11: Guidance on usability*" (100). Davis (170) developed measurement scales for assessing perceived usefulness and perceived ease of use. These scales were used as inspiration in the development of questionnaires. Abran et al proposed a consolidated and normative model for evaluating software usability (171). Their measurement proposals were also an inspiration in the development of usability measures. DeLone and McLean was yet another source of inspiration (172). In their "Information Systems Success Model" (see Figure 16), DeLone and McLean describe the conditions for a successful information system.

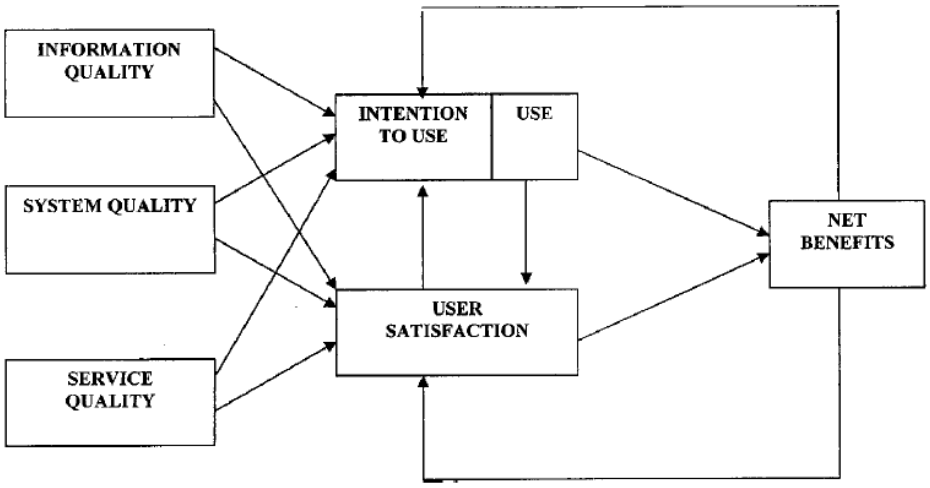


FIGURE 16 INFORMATION SYSTEM SUCCESS MODEL BY DELONE & MCLEAN

The model indicates the association between several quality measures, - Information Quality, System Quality, Service Quality - and the success dimensions - Intention to Use, Use and User satisfaction - and their relation to Net Benefits. In our work, we were inspired by the dimensions and relations in the model which define and qualify objectives and outputs from the simulations. Clinical simulation techniques provided the substantial basis to our method (27).

The metrics of assessment were based on the criteria and purpose of the assessment. ISO standard 9241 – part 11 (100) recommends making an evaluation to encompass at least one of each of the three usability measures included in the standard. These measures are interpreted by Davis as perceived usefulness and perceived ease of use (170), and by DeLone and McLean as intention to use/use and user satisfaction (172). These two dimensions constituted the basis for our assessment measures.

During the clinical simulations, two measurements were monitored; 1) fulfilment of tasks and 2) difficulties in using the information systems (ease of use). As described in ISO 9241 – part 11 (100), the relative importance of components of usability depends on the context of use and the purpose. There is therefore no general rule for how measures should be chosen or combined. The choice of measures and level of detail of each measure depends on the objectives, and the relative importance of each measure to the goals had therefore to be considered. Patient safety is not, however, a direct component of the ISO standard.

When it is not possible to obtain objective measures, subjective measures (based on the user's perception) may provide an indication of effectiveness and efficiency. Observations made during the clinical simulation were therefore supplemented by questionnaires. The questionnaires were primarily based on the work done by Davis (170). To assess patient safety issues, the evaluation criteria were partly based on adverse events and experiences of the use of CIS in the regions. The criteria were mapped to the areas of the assessment.

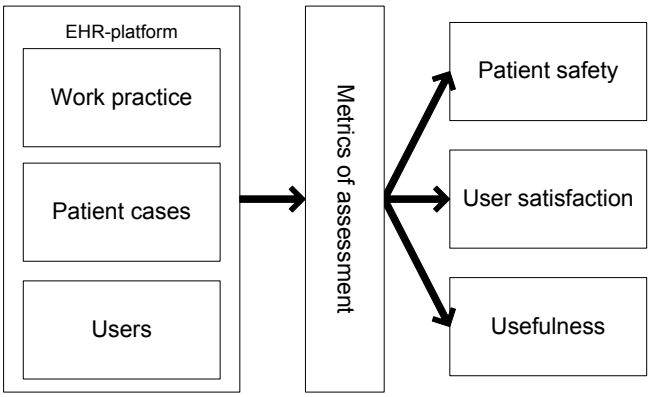


FIGURE 17 MODEL FOR ASSESSMENT OF USE IN PROCUREMENT

Figure 17 shows a model for the assessment serving as the specification of the assessment set-up. To the left is the object that is to be assessed, i.e. the EHR platform, in the middle the means by which the results are to be collected, i.e. the metrics of assessment, and to the right is what will be assessed ,i.e. patient safety, user satisfaction and usefulness. These dimensions from DeLone & McLean, *intention to use/ use* and *ease of use*, may be interpreted in the ISO 9241 standard (100) as *effectiveness* and *satisfaction*. In our model, the terms *usefulness* and *user satisfaction* are used. As patient safety is a vital dimension in healthcare it is brought in to our model. It was not possible to assess efficiency as resources expended in relation to effectiveness would require a high degree of proficiency among the participating clinicians.

Working with assessment on such a large scale made it clear that prioritization is a key factor. In order to comply with the complexity of the scope of the assessment as well as with the deadlines in a procurement process, it was imperative to remain focused. The assessment had to be conducted over a very short period of time and the results had to be collected, analyzed and pre-

sented without delay. The assessment also had to cover a variety of stakeholders with varying tasks and diverse aspects of clinical use of the EHR platform. There is a risk that the assessment process will not provide a complete picture of the system in use. We have not been able to develop a method for assessing the long-term effects, i.e. what happens when the clinicians have become accustomed to the system. When clinicians are accustomed to the system, other features may be prioritized.

Not all groups of healthcare professionals were involved in the clinical simulation. To compensate for their absence, other groups of professionals, such as therapists and midwives, might have been included as observers in the simulation setup along with other stakeholders, such as risk managers, quality managers and clinical managers. As described in the requirement evaluation case study (149), observing clinicians are able to reflect on their own use while observing colleagues doing simulations. Observations of how and for which purposes other healthcare professionals use an information system are a valuable supplement to performing the simulations yourself. Such observations may also be alternative courses of action , when it is not possible for all clinicians to participate personally in the simulations (149). In the procurement study the observer clinicians had the opportunity to dissociate themselves from the simulation and reflect on the usefulness of the system. The use of multi-disciplinary teams enabled the participants to assess the system's capacity to support multi-disciplinary documentation and work processes.

Tasks, work practice and users are core elements in the context of use. We were aware that the scenarios did not cover all possible aspects of work practice but, by mapping these three dimensions in the scenarios, we ensured that different contexts were represented in them. The choice of scenarios did, however, reflect the business strategies. In one case, the need for test data was too time-consuming to be used for clinical simulation.

In a public procurement process, suppliers must be treated uniformly. It was essential that the clinical simulations were performed uniformly, contrary to what is common practice in explorative studies for design purposes. The scenarios had to be minutely described and the roles of the users and patients had to be followed to the letter.

The procurement process implied the following challenges to the assessment: 1) the results had to be comparable; 2) the assessment of the different EHR platforms had to be homogenous; 3) the process had to be transparent; 4) time to conduct and report on the assessment was very limited; 5) the assessment data had to be easily collectable and quickly made available for analysis. The size of the actual project from which this case study evolved was responsible for three further challenges: 1) all aspects of the EHR platform had to be covered, 2) all clinical specialities had to be dealt with, and 3) all possible types of users had to be considered and preferably included in the assessment.

The challenge was to cover key aspects of the EHR system without compromising more complex and peripheral aspects. Selection and prioritization were key elements at the risk of omitting essential parameters. On the other hand, this was necessary in order to make an assessment that could, on the one hand, embrace the full variety and complexity of system use and user satisfaction within an EHR platform covering several hospitals and ten thousands of users and, on the other hand, could meet the stringent demands of a public procurement process. Clinical simulation was just one sub-method applied in the assessment process, and it had to be supplemented by other assessment activities. The clinical simulation assessment method was, however, an important opportunity to assess the usefulness and ease of use of the systems and also a chance

for users to voice an opinion. They will after all be using the system selected on a daily basis in the years to come.

Regarding the eligibility of clinical simulation as a method to uniformly assess human factor issues in PPPs, we found that the method was indeed useful and made it possible to assess qualitative aspects that were otherwise difficult to specify and assess (53). Careful attention was, however, essential in order to develop textual requirements that could provide a solid foundation for the assessment criteria. Clinical simulation proved to be an adequate method for assessing user satisfaction as it gave the users firsthand experience of the EHR platforms in a close to real life setting, focusing on the interaction between technology, users and work practice. Although it was difficult for the clinicians to become proficient at using the EHR platforms within the short assessment period, they were able to state reasons for good and bad user experiences with each of the three EHR platforms. The lack of proficiency might be compensated for by training the simulation facilitator more extensively in the use of the EHR platforms and providing comprehensive guidance on platform functionality during the simulations. Compared with other methods, such as heuristic inspection and low fidelity usability evaluation, clinical simulation takes the clinical context into account. Other methods tend to focus on only one or two topics without their clinical context. Heuristic inspection focuses only on the user interface and low fidelity usability testing focuses on technology and specific tasks for single users. These methods may, however, complement clinical simulation in creating a rigorous assessment of the user interface.

Regarding usefulness, the clinicians found that the clinical simulation facilitated an understanding of the extent to which the EHR platforms were able to support daily clinical work practices. At first there was some reluctance to working in interdisciplinary groups but this proved to be essential to facilitating a richer understanding of the functionality of the EHR platforms in collaborative work situations. This would not have been possible in a low fidelity usability test, in which a single user solved a single task.

Patient safety issues proved to be especially difficult to assess due to the fact that many patient safety challenges lie in the details and are triggered by adverse events and disturbances. In one of the three solutions, it was possible to document a note but it was very difficult to determine whether anything had been documented as it only appeared as an underline or mouse-over. During the simulation, it became very obvious that the clinicians failed to notice this, which meant that they might have overlooked important information. In another case, it turned out that information about allergy was not always automatically transferred to all other allergy fields. Potential patient safety hazards like these did not become evident before the information systems were actually used in clinical simulations. It can therefore be difficult, if not almost impossible, to pinpoint such issues beforehand. They are necessarily encountered along the way. Clinical simulation is, however, an appropriate method by which to assess patient safety issues as it provides a comprehensive view of the information system taking into account the correlation between IT, work practice and adverse events. We recommend, however, that in order to gain in depth views on patient safety issues this should be conducted in close collaboration with patient safety experts.

Creating an assessment process that was both transparent and uniform and which ensured not only that the scenarios were realistic and relevant for the customer but also that the vendors were involved in decisions related to scenarios, test data and configurations, was a difficult balance to strike. The assessment was not blinded. When users are involved, there is a risk of mutu-

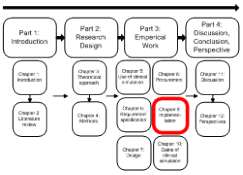
al influence. This may be dealt with in the design of the simulation set-up. However, we found that the benefits of involving users across specialties and professions outweighed the difficulties.

Clinical simulation made it possible to assess qualitative aspects that were otherwise difficult to measure, like patient safety and human factors (53). In a requirement specification, the purchaser describes something that already exists. In return he receives a textual description, which he is required to evaluate by giving points based on a standard evaluation method. . The use of clinical simulation in the early phases of the procurement process may improve assessment of the systems on offer and make it possible to expose and assess qualitative aspects, such as human factor aspects, patient safety and support of work practice (149; 168). Patient safety issues are difficult both to describe in sufficient detail and to assess without involving clinical context and work practice either in real life or in a simulated set-up. In PPPs, a real-life assessment is seldom possible, although clinical simulation is a very suitable substitute. To set up a clinical simulation-based assessment in a PPP was a huge task. However, bearing in mind the immense impact of the procured platform on the healthcare organization, we believe that a clinical simulation should always be undertaken. The value of making such an investment on a thoroughly enlightened base cannot be overestimated. The assessment may further be applied as a basis on which to discuss future challenges and opportunities during platform implementation(173).

A clinical simulation-based assessment of a PPP was beneficial for gaining insight into user satisfaction, usefulness and patient safety. Conventional methods focus on the relation between users and user interfaces without involving the clinical context. Clinical simulation illuminates the relation between users, technology and work practice and hereby provides deep insight into the system in question. It remains difficult, however, to assess clinical decision support systems using clinical simulation as clinicians make fewer errors during simulation than they do in real life (30).

The evaluation process we applied made it possible to systematically assess each of the platforms and their differences. Clinical simulation was eligible in a PPP of CIS as a supplement to other assessment activities. We can recommend the use of clinical simulation as a method by which to assess user satisfaction, usefulness and patient safety. It provides an excellent basis for user involvement and also gives the users an opportunity to express an opinion. We recommend, however, that clinical simulation is supplemented by low fidelity usability evaluation and heuristic evaluation in order to assess minor variances in ease of use.

This section has discussed the use of clinical simulation in assessing activities in a procurement process. Clinical simulation is suitable for use in a CIS procurement process as a supplement to other activities. Clinical simulation is recommended as a method by which to assess user satisfaction, usefulness and patient safety. It provides an excellent basis for user involvement and also gives the users an opportunity to express an opinion. The next section discusses the use of clinical simulation in application assessment in work practice.



9 RESEARCH FINDINGS – IMPLEMENTATION

In this section I will discuss the research question "*What are the potentials of using clinical simulation to acquire knowledge of implementation?".* Publication K:*"Identification and prevention of patient safety hazards"* is related to this research question and describes how clinical simulation can be used for both evaluation of CIS and the acquisition of knowledge prior to implementation of these systems. The publication is related to the Implementation case study, which is described in detail in section 4.1.5. As the title indicates, the publication focuses on patient safety issues but also presents how clinical simulation can be used to evaluate information systems and work practices as well as the relationships between them.

One of the purposes of using clinical simulation in relation to implementation was to investigate the support of clinical practice of an information system. The need for a high degree of fidelity on all four fidelity dimensions (see section 4 *Methods* page 27) increases in line with the need for realism throughout the simulation (61). If the purpose is to evaluate training materials and the need for information in connection with an implementation, the same applies to training of clinicians prior to the simulation. If the purpose is to evaluate, then all aspects must be as realistic as possible. In the implementation case study, the goal was to determine whether the information system should be implemented at the hospitals. The need for fidelity was therefore high.

The aim of the implementation case study was to investigate how a standard information system, "OPUS Inbox" supports clinical practice, and to identify potential patient safety hazards prior to its implementation. In addition to implementation aspects such as training and information, the purpose was also to evaluate future work practice, the relation between technology and existing work processes, and the extent to which clinical simulation may be applied as a proactive method to identify and evaluate potential patient safety hazards prior to implementation (162). Clinical simulation as a method was evaluated by means of interviews with the project manager, a manager from one of the pilot hospitals, and an expert from the patient safety unit. An analysis of work practice conducted prior to the clinical simulation revealed that there were significant differences between the hospitals, between the patient wards, and the outpatient clinics - and indeed also between the individual healthcare professionals. Furthermore, the design of future work practice presented a number of challenges and it was not possible to design a generic work flow to cover both patient ward and outpatient clinic. This was to some extent due to differences between local work flows but also due to the fact that the information system functionality did not provide adequately support for work practice.

The clinical simulation identified many uncertainties concerning work flow, handling of responsibility, and other organizational and technical challenges. The process also showed that the choice of observers is very important. Each expert focuses on his or her own field. For this reason, observers must be chosen carefully and bearing in mind the purpose of the evaluation. During the simulation there were no observers with patient safety expertise. The simulation results were presented to patient safety experts, who identified many patient safety issues. Several organizational and technological issues, which were regarded as inconveniences by others, were detected as patient safety risks by the patient safety experts. High fidelity functionalities, such as

integration to other information systems, revealed patient safety issues; e.g. notes related to a test result were not shown in relation to the test result in OPUS Inbox. The physician could only find the notes in the lab system. Apart from many negative findings, there were also positive findings, including improved overview of laboratory test results and no paper test results were left lying around, at the risk of disappearing.

The evaluation was formative and primarily used as a learning process. Formative evaluation studies can facilitate system adoption and utilization (174) and aim to improve a system during its development or implementation, while summative evaluation focuses on evaluation of a system that is already up and running (175). Formative evaluation may identify potential problems, such as patient safety issues, during the development phase and thus provide opportunities to improve a system as it develops. In the simulation study, the results of the formative evaluation regarding patient safety issues and work practice for handling laboratory test results was presented and discussed at meetings with the various stakeholders, i.e. the patient safety unit, the quality unit and the implementation departments. Precautions were taken in relation to patient safety matters and work practice. Many of these precautions were subsequently implemented, regardless of the implementation of information system.

It is very often unclear whether errors occur due to the technology itself or due to human error on the part of the individual healthcare professional. Incidents usually occur in the interaction between humans, technology and work practice. The correlation between human, technology and organization is visualized during clinical simulation, which therefore clarifies all three aspects. More conventional usability evaluations tend to visualize the interaction between the user and the technology but do not include work practice context (27; 38; 48). By including all three aspects (humans, technology and organization), patient safety challenges were revealed as well as organizational and technical challenges. New work practice in itself may also lead to unintended incidents. This was also revealed during the clinical simulation.

Clinical simulation makes it possible to expose and focus on patient safety matters. The use of patient safety experts as observers makes it possible to identify the risks and challenges. In the implementation study, patient safety experts were not used as observers. The simulation evaluation report was subsequently shown to the patient safety experts. Having patient safety experts observe the simulation would have improved the outcome considerably. These experts have great experience of what can go wrong and are able to focus on these matters during the simulation. They obseve the interaction between the user and the interface of the technology but just as much the interaction with the technology in the clinical context. Inclusion of clinical context is one of the most powerful elements in clinical simulation. By allowing clinicians to use new technology in the way it is supposed to be used, patient safety issues become visible. Clinical simulation enables visualization of technology in connection with clinical context without endangering patients (53).

To expose cognitive and socio-technical issues, fidelity needed to be high. The overall simulation fidelity configuration affects how the realism of the simulation experience is perceived (61). Cognitive aspects of work practice relate to the clinical context and therefore depend on the degree of environment and task realism (160). Socio-technical aspects and patient safety matters lie in the intersection between user, organization and technology (176). Fidelity configuration must be high on all four dimensions.

Traditional information systems are often designed around an idealized model of the tasks and workflow, and failures in information systems are often blamed on human social and cultural

"barriers" to technology adoption (15). The implementation case study revealed differences between such an idealized model of the task that needed to be accomplished and the way in which clinicians were actually working. Some of the differences were due to local interpretations of the regional guidelines and one of the conclusions reached was that the regional quality unit should develop a regional standard for signing off test results. Another issue lay in the fact that the information system was a standard system which did not provide adequate opportunities to configure the system to match the local setting. If work practice differs from department to department, local configuration is a requirement. A regional standard was introduced to resolve this issue.

Clinical simulation did not reveal all the challenges that were due to the information system. The challenges about handling pre-ambulatory test results and unusual test results were not exposed during the clinical simulation. Clinical simulations are no better than the scenarios and patient cases they cover. In the implementation case study, the scenarios during the simulations did not include unusual results or the pre-ambulatory test results. Clinical simulation involves an inherent risk of giving an idealized picture compared to real life. When planning and designing the evaluation, it is important to take such matters into account. Another aspect was the purpose of the evaluation and the relation between existing and future work practice. What is to be evaluated - future or existing work practice? And do the end-users comprehend and approve of the new work practice? Furthermore, if the existing work practice in a department does not follow the existing guidelines, this may influence the evaluation of the interaction between future work practice, end-users and technology as well as subsequent implementation.

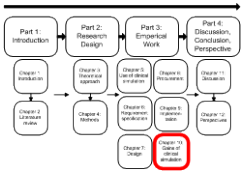
To what extent is it possible to allow technology to be the entry point for improving quality? Should such projects be regarded as technology projects or organizational development projects? The balance is delicate and should be carefully defined in each project. The "'OPUS Inbox"' project failed to achieve that balance, partly due to the technological limitations. For the project to succeed, the technology would have had to have supported future work practice more effectively, and made it easier for the clinicians to comply with it. Subsequent observations showed that nearly 300 test results were not acknowledged. The project evaluation recommended that a regional guideline should be developed and implemented before implementing new technology.

Similarly, muddled work flows became clear during the simulation and observers focusing on work flows agreed that a further work flow analysis was needed. This resulted in revision of the future work practice. The sheer range of differences in existing work practices at hospitals, departments, wards and clinics meant that it was not possible to design generic future work flows. As a result, the regional quality unit was asked to design a regional guideline for handling laboratory test results. Many of the issues found during the simulation were addressed before the pilot implementation, and those that were not solved were observed again during the pilot implementation. However, not all challenges were revealed during the clinical simulation. Issues such as the handling of pre-ambulatory test results and unusual test results were not identified. In short, clinical simulation cannot replace a pilot implementation, but should rather be regarded as a valuable supplement.

Patient safety issues are difficult to assess due to the fact that many patient safety challenges lie in the details and are triggered by adverse events and disturbances (176). The results of the case study showed that clinical simulation took the clinical context into account, while other methods,. e.g. heuristic inspection focus on the user interface. Low fidelity usability testing focuses on technology and specific tasks for single users. It can therefore be difficult, or almost impossible, to pinpoint patient safety hazards using these methods. Clinical simulation provided a compre-

hensive view on the information system taking into account the correlation between IT, work practice and adverse events, and is therefore a more appropriate method for assessing patient safety issues. Clinical simulation is costly and time-consuming (30) and the purpose of simulation studies should be planned carefully.

This section discussed clinical simulation for application assessment in work practice. In the case study clinical simulation revealed organizational and technical challenges as well as patient safety issues. The next section discusses potential benefits and limitations inherent to the use of clinical simulation.



10 RESEARCH FINDINGS –GAINS FROM USING CLINICAL SIMULATION

In this section, I will discuss the overarching research question RQ0 *" What might be gained from using clinical simulation during various phases in the development of clinical information systems?"* and examine the opportunities and potential benefits as well as the challenges and limitations of using clinical simulation. This will be done with reference to all five case studies and the related publications. Table 7 (below) describes the potential purposes, benefits, limitations and the types of results that have come out of the five case studies.

TABLE 7 POTENTIAL AND CHALLENGES OF CLINICAL SIMULATION IN VARIOUS PHASES

Topic	**Requirement specification**	**Design**	**Procurement**	**Implementation**
References	(149; 160)	(145; 161; 173)	(31; 177)	(162)
Purposes	Analysis and evaluation of: • work practice • user requirements • cross-disciplinary requirem. • handovers • cross-organizational systems • efficiency, satisfaction and feasibility	Formative evaluation of new technology Investigation of impact of new technology and work practice	Assessment of • of tenders • qualitative aspects; patient safety, human factors, user satisfaction User involvement	Evaluation of: • design • support of work practice • technology in work practice and • training program • existing & future work practice Formative evaluation Summative evaluation
Types of results	Requirements: • context-sensitive • user requirements • cross-disciplinary Work practice information Unintended benefits Organizational challenges and concerns Potential new users and ways of using technology	Visualization of • interaction with IT system • effect on work practice • similarities and differences between specialties and parts of an organization Knowledge of: • beliefs and practices of others • new practical challenges Formative evaluation of design and support of work Translation of pros & cons of technology & work practice	Subjective evaluation of user satisfaction Insight in EHR platform support of patient encounters Stated reasons for good and bad user experience Assessment of qualitative aspects; patient safety and human factors Cross-disciplinary assessments	Effect on work practice Organizational challenges Technical challenges Input for design of technology Input for redesign of work practice End-users understanding of system model Patient safety issues Intended and unintended potential benefits

Topic	Requirement specification	Design	Procurement	Implementation
Challenges and limitations	No richness of interaction in low fidelity prototypes Not all possible applications of technology may be covered	Costly and time-consuming Is not a substitute for pilot implementation Does not cover • long periods of time • all parts of an organization • all parts of work practice • all possible events and patient cases	Difficult to assess • minor variations of use • objective user satisfaction Difficult balance to ensure • transparent and uniform assessment process • realistic and relevant scenarios Assessment not blinded Lack of complexity • in patient cases • number of patients Less stressful environments Short introductions entail • many interruptions • difficult to achieve proficiency Difficult to assess aspects other than end-user aspects	Purpose must be clear regarding assessment of existing or future work flow Challenging to allow assessment of IT system based on use of new work flow Does closely resemble the use of technology → no substitute for pilot implementation Clinicians make fewer errors during simulation than in real life
Achievements	Involvement of clinical context Involvement of user Safe experimental setting in a realistic clinical context Appreciation of new concepts Visualization of interaction between different groups of healthcare professionals Understanding of other healthcare processes Knowledge of • difficulties in understanding new concepts • cross-organizational work processes • organizational issues, challenges and potential benefits that need to be addressed Setting for discussion and exploration of cross-organizational work flow in new technology	Alignment of expectations, mutual acceptance and understanding Ownership, involvement and inclusion of users Creation of new knowledge of e.g. use of new technology Learning space, where knowledge of other parts of an organization or other organizations is acquired Opportunity to observe and discuss own practices as well as others' practices An approach to tackle tensions between divergent viewpoints Shared understanding and common ground for discussion and negotiation Visualization of perception gap Transformation of knowledge and attitudes	User involvement Assessment across specialties and healthcare professions Clarification of differences in clinical requirements Assessment and reflection on different CIS First-hand experience for end-users in a close to real life setting, focusing on the interaction between technology, users and work practice Deep insight into CIS and how the systems support work practice Deep insight into needs and concerns related to organizational implementation Comprehensive view, correlation between IT, work practice and adverse events	Visualization of • possible work-around • potential patient hazards without endangering the patient Safe space for analysis and experimenting with future work practice and use of technology

The main challenges and concerns in using clinical simulation were:

- the purpose must be rooted in the organization as the purpose impacts the choice of scenarios, users and observers and the need for fidelity (178)
- choice of
  - scenarios determines what part of work practice is evaluated (178)
  - users determine the requirements and needs, against which the information systems will be evaluated (31)
  - observers determine the focus of the evaluation (162)
  - fidelity reflects the performance of the simulation (160)
- lesser complexity in work practice and short time frame
- clinical simulation does not reflect
  - the social-technical impact over time (31)
  - effectiveness (31; 149)

The main achievements of using clinical simulation were:

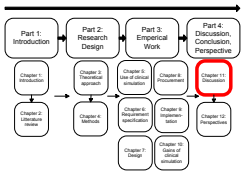
- user involvement (31) and involvement of clinical context (162)
- controlled environments for experiments and formative evaluation (149)
- evaluation environments for addressing cross-sectorial and cross-functional topics (149)
- common ground to gain shared understanding (161) and organizational learning space (161)
- strengthens dialog with vendors (31)
- visualization of unintended benefits and challenges (149)
- rich understanding of functionality by working in interdisciplinary teams (31)

As described in my findings and in Table 7, clinical simulation may be used in different activities in the user-centred design cycle (52) (described on page 25) and for various purposes during all phases of the development life cycle of information systems. The purposes and different aspects that were evaluated varied throughout the five case studies. Table 8 presents different evaluation aspects and shows that clinical simulation may be used to assess various aspects. The different assessment aspects and the need for fidelity when conducting clinical simulation will be discussed in the next section.

TABLE 8 EVALUATION ASPECTS IN THE CASE STUDIES

Evaluation aspects	Requirement analysis	Requirement evaluation	Design	Procurement	Implementation
Human factors	x	x	x	x	x
Patient safety		x	x	x	x
Usability		x	x	x	x
Work practice	x	x	x	x	x
HCI			x	x	x
Common ground	x	x	x	x	x
Requirem.	x	x	x	x	x

This section discussed the opportunities and benefits as well as the challenges and limitations of using clinical simulation. The section presented a structured overview of potential purposes, challenges and limitations, and achievements in various phases of the development cycle together with different types of results. The next section discusses the overall findings of my research.



11 DISCUSSION

By embracing technology, users and the clinical context (e.g. work practice and patient cases), it was possible to analyze (160) and evaluate (31; 149) new technology in close to real situations without endangering patient lives (162). Methods such as low fidelity usability evaluation (102; 179) and functional testing (green oval in Figure 18) explore the human-machine interface (121). The human-software interface (122) discussed by Hendricks focuses on single end-users' interaction with the technology without taking the medical context into account as it omits e.g. acting patients, interruptions, colleagues and the physical environment. The low fidelity relates to environmental fidelity, whereas equipment and functional fidelity may be high. Task fidelity may be high but only focuses on tasks involving a single user. Inadvertent challenges and benefits in relation to organization and work practice as well as patient safety issues may not be revealed when conducting traditional low fidelity usability studies.

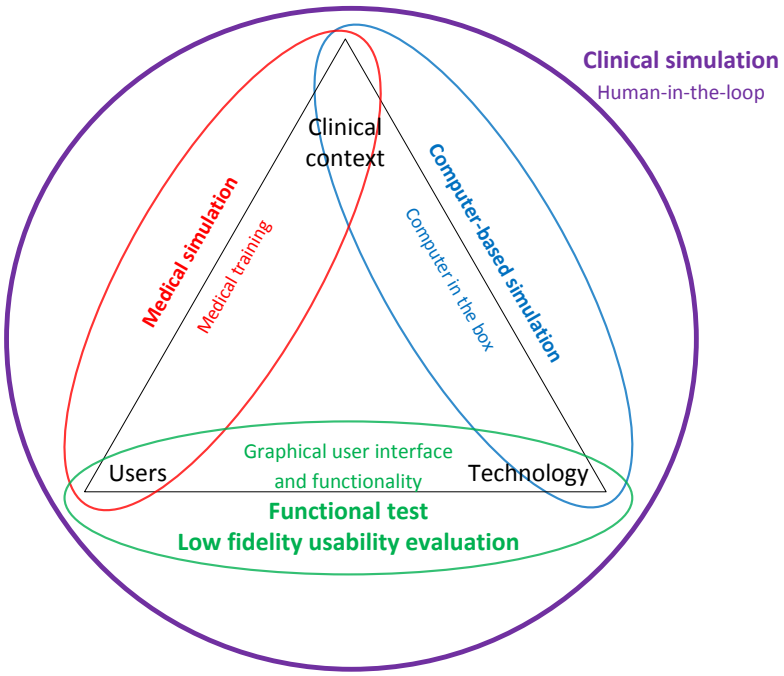


FIGURE 18 FOCUSING ASPECTS IN CLINICAL SIMULATION

Medical simulation (red oval in Figure 18) used for purposes of training healthcare professionals (40) focuses on the clinical context and the clinicians (users), but does not focus on technology itself because medical simulation is used for training medical skills, social-oriented work and cognitive-individual-oriented aspects of clinical work practice. Computer-based simulation (blue circle in Figure 18) focuses on the "*computer-in-box*" simulation and extends from clinical context to technology, where the clinical context is simulated without involving real users. Clinical simulations (purple circle in Figure 18) combined clinical context, users and technology, revealing the relationship between the three areas and focuses on sociological aspects in the socio-technical interaction; "*human-in-the-loop*".

By embracing all three aspects, with the limitation of e.g. lesser complexity in work practice and short time frame, the "*human-in-the-loop*" approach converges with the human factor aspects' understanding of interaction between humans and other elements of a system, such as e.g. technology, procedures, persons and physical environments (116). As presented in Table 9, investigation of the remaining interfaces described by Hendricks (70; 120), i.e. human-environment interface, human-job interface and human-organization interface technology, required high environmental and high task fidelity.

TABLE 9 NEED FOR FIDELITY IN EVALUATION OF HUMAN FACTORS

Human factor interfaces technology vs fidelity dimensions	**Environmental fidelity**	**Task fidelity**	**Equipment fidelity**	**Functional fidelity**
Human-machine interfaces technology	Low	Very low	Very high	High
Human-environment interfaces technology	Very high	High	Low	Very low
Human-software interfaces technology	Very low	Low	High	Very high
Human-job interfaces technology	High	Very high	Low	Medium
Human-organization interfaces technology	Very high	Very high	Very low	Low

Types of results differ according to the degree of the different components of fidelity. The choice of fidelity should therefore reflect the purpose of the clinical simulation. In Table 10 the different degrees of the fidelity dimension from the two case studies concerning requirement specification are presented together with the different types of outcomes from the studies. In the requirement evaluation study, the degree of equipment and functional fidelity was high, and this resulted in more advanced knowledge of the use of technology and the organizational benefits and challenges due to the visualization of technology applied. Both studies revealed latent user requirements related to context-sensitive and cross-disciplinary needs. In the requirement evaluation study, however, the results were richer as they revealed several examples of organizational potential, e.g. using the PCM for communication and coaching across sectors. Meanwhile the requirement analysis study revealed requirements for the information system, e.g. the need for different modes in a CIS to reflect the work flow.

TABLE 10 DIFFERENCES IN FIDELITY DIMENSIONS AND TYPES OF RESULTS IN REQUIREMENT CASE STUDIES

Fidelity dimensions	**Requirement analysis**	**Requirement evaluation**
Environmental fidelity	High: realistic environments and 'acting patients'	High: realistic environments and 'acting patients'
Task fidelity	High: Real scenarios	High: scenarios based on realistic patient cases
Equipment fidelity	Low: cardboard box mock-up	High: electronic prototype
Functional fidelity	Low: post-it labels and WoO approach	High: fully functional prototype with faked integrations
Facilitating method	Obser-view	Think-aloud

Fidelity dimensions	Requirement analysis	Requirement evaluation
Type of results	User requirement Knowledge of work practice	User requirement Knowledge of work practice Evaluation of usability Potential new users and use of technology Unintended benefits Organizational challenges

There are a variety of answers to the question, "how low can fidelity go?" depending on the purpose of the clinical simulation and the different fidelity dimensions. In the case study concerning requirement evaluation, the purpose was to evaluate the usefulness of a PCM looking into more organizational aspects, and therefore there was a need to visualize the use of the application in an organizational setting.

In the case study of the analysis of requirements, the fidelity of the task content had to be rather high, although there was no need for high fidelity in the execution of the tasks. High fidelity environments are required to help increase clinicians' perception of realism. As one of the clinicians in the requirement analysis case study said: "*it is the patient who makes the scenario come alive*". The purpose of the simulation study was to acquire knowledge of user requirement in a specific area of clinical work practice, whereas the actual interaction with a computer or an information system was less important. The need for equipment and functional fidelity was therefore rather low. The low degree of technical fidelity meant that no limitations were imposed in the guise of well-known functionalities and technology. This was actually beneficial in this case. However, if the purpose of the clinical simulation had been to evaluate the usability of a specific device or information system, the need for equipment and functionality fidelity would have been higher. When specifying user requirements, clinical simulation cannot stand alone but should be used as an add-on to other methods, such as field studies and workshops (142).

As described by Beaubein (144) and Dahl (61), the four dimensions of fidelity may be seen as two types of fidelity; 1) psychological fidelity and 2) physical fidelity. Another view could be to group the four dimensions in two fields, i.e. a) clinical fidelity and b) technical fidelity. Environments and tasks reflect the clinical set-up in a simulation, whereas equipment and functionality reflect the technical set-up. The two different views are presented in Figure 19.

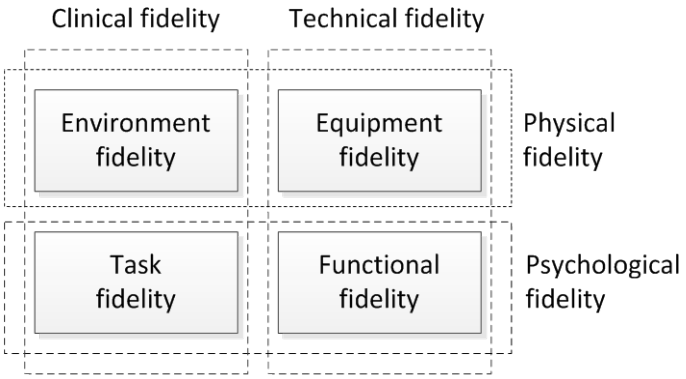


FIGURE 19 VIEWS ON SIMULATION DIMENSIONS

In Table 11, environmental and task fidelity are merged into "clinical fidelity", whereas functional and equipment fidelity are merged into "technical fidelity". The figure presents the different need for fidelity for various activities and purposes. The two lower areas with low clinical fidelity are not relevant in relation to clinical simulation, as clinical simulation relates to real users performing realistic tasks in realistic environment. As mentioned earlier activities in the two lower areas should be used as supplement to clinical simulation as they focus on other areas.

TABLE 11 DEGREE OF FIDELITY IN VARIOUS ACTIVITIES

		Technical fidelity	
		Low	**High**
Clinical fidelity	**High**	Experiments Analysis Formative evaluation • *Design*	Formative evaluation • *Design* Summative evaluation • *Procurement assessments* *Application assessment in work practice*
	Low	Heuristic evaluation Mock up test	Functional test Technical test Usability evaluation

In Dahl's four fidelity dimensions, by there is no direct reference to the degree of fidelity concerning the actual performance of the simulation. The requirement analysis case study indicated that task fidelity might be categorized into two parts: one part related to the content of scenarios and tasks and another part related to the execution of scenarios and tasks. Although task and functional fidelity are high in both cases, acceptance of the simulation may vary between a simulation where the facilitator has conducted "obser-views" during the simulation and a simulation where there were no interruptions. It can be argued that the two cognitive fidelity dimensions cannot be high when "obser-views" are conducted during the simulation, but a fifth dimension could be added to fully describe simulation fidelity.

11.1 CONCLUDING NOTE

The complexity of organization and work practices in healthcare creates challenges regarding the choice and application of methods used in developing and implementing CIS (34). The complexity of health organizations and the various types of healthcare actors complicates the specification of user requirements and the design and implementation of CIS. These issues in eHealth influence the cost and resources invested in the acquisition and implementation of new technology at the hospitals as well as their subsequent adoption, and may cause a lack of acceptance and understanding among end-users. Clinical simulation can be a useful means by which to create shared mental models and shared understanding of user requirements, work practice and organization requirements. Clinical simulation is a useful method by which to analyze these issues. It serves as a reflective means by which to improve solutions to the problem (161). Organizational differences can be overcome and shared understanding is made possible by achieving a mutual clinical agreement on the basis of shared mental models and mutual discussions.

Involvement of end-users and other parts of the organization greatly improves both the design and implementation of new technology and the design and implementation of future work processes (145; 161). If users are not adequately involved in these processes, the new technology developed may endanger patient safety and result in inadvertent events and increased mortality (162). Acceptance of new technology may be earned by giving the different communities of practice a chance to voice an opinion and thereby support the acceptance and use of the new technology. Studies show the possibilities in having different healthcare actors to participate in clinical simulation and subsequently debriefing discussions (30; 149). The case studies reveal that clinical simulation can be useful in different activities in the human-centred design cycle.

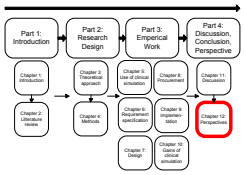
Unintended benefits may not be revealed prior to implementation and their full potential may not be achieved (149). Clinical simulation offers an opportunity to create a space in which healthcare professionals working in different locations or healthcare sectors can meet and exchange knowledge about work practices and requirement needs (31; 160). This approach proved effective in identifying important unintended benefits and challenges (149), and acquiring knowledge of how new technology may impact work practices (161) and patient safety issues (162).

The resources invested in preparing and performing simulation studies are quite exhaustive, although the cost depends on the desired degree of fidelity. It is therefore essential to adjust the cost of creating a realistic setting to the aims of the evaluation and simulation (27; 59). On the other hand, cost savings are difficult to quantify as benefits, such as saved lives, are difficult to measure. However, many of the results of the simulation studies in the five case studies would not otherwise have been revealed.

Much has been learned during my research. New knowledge has been acquired about the use of clinical simulation in a procurement process and about clinical simulation as a boundary object in the development of CIS. This thesis offers a thorough description of a methodological approach for planning, preparing and conducting clinical simulation and of the use of clinical simulation in various phases of the development life cycle of CIS.

My short reply to the question: *What might be gained from using clinical simulation during various phases in the development of clinical information systems*? is that clinical simulation can involve users and the clinical context in human-centred activities throughout the various phases in the development cycle and contribute to the development of safe and useful CIS.

This section has discussed the overall findings in my research. Related areas may need to be investigated further. These areas are introduced in the next section.



12 PERSPECTIVES

Simulation conducted in the same way as clinical simulation, where end-users use new technology in realistic set-up whilst doing realistic tasks, may beneficially be used in other high risk areas in the same way as clinical simulation is used in healthcare. Potential areas could be pharmacy, fire departments and aviation. Other spheres within healthcare than those described in this thesis could make use of simulation. My research has focused on CIS in a hospital setting but areas, such as primary nursing and general practitioners could benefit from the principles and techniques of clinical simulation. As such, clinical simulation might be used as a gatekeeper function throughout health IT.

As healthcare technology moves into patients' homes, simulation could also be used in private settings. As patient-oriented functionalities are part of the new EHR platform in the Capital Region of Denmark and Region Zealand, these and similar issues will have my attention. A set-up with a one-way mirror and cameras mounted in the ceiling is not appropriate in a private home. Mobile cameras and intercom must be used as part of the technical set-up during the simulation. This mobile technical set-up has been used in a simulation study at one of the regional hospitals. The results were promising although there remain some technical challenges regarding band width. The study showed that using a mobile set-up in a hospital department made it easier to focus on an entire patient flow between different hospital units as it was easier and more flexible for the clinicians to attend the simulation than it would have been if they should have been removed from their local settings. The simulation and subsequent debriefing interview were vivid for the participants and the user involvement was more apparent to the rest of the staff.

Other fields, such as biomedical engineering, could use clinical simulation to analyze and evaluate biomedical equipment. Biomedical equipment is covered by the CE marking regulation (180) where e.g. evaluation of usability is concerned. IT solutions are extensively applied to the use of biomedical equipment why areas in health IT are also being included, and simulation-based evaluations might be also be valuable in relation to the procurement and purchase of medical technology and in aligning the different types of equipment scattered around the hospitals.

Clinical simulation in examination of adverse advent might also be useful, as it is possible to stage adverse event scenarios with a view to creating more controlled and safer environments.

The areas mentioned above are all recommended as areas for further research.

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13 APPENDICES - OVERVIEW OF PAPERS

Appendix 1: Jensen S, Lyng KM, Nøhr C. The role of simulation in clinical information systems development. Stud Health Technol Inform 2012;180:373-7.

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Appendix 6: Jensen, S., Kushniruk, A. Boundary objects in clinical simulation and design of eHealth, Health Informatics Journal 2014

Appendix 7: Jensen, S., Nøhr, C., Kushniruk, A. 2014. Clinical Simulation: A method for Development of Clinical Information Systems,

Appendix 7: Jensen, S., Hermansen, B., Nøhr, C., 2014 Identification and prevention of Patient safety hazards - not published